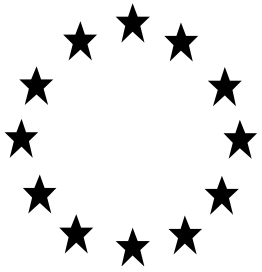
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS

Product type 3

Active substance: **Iodine, including PVP-iodine**

Case Number in R4BP: **BC-WU019429-99**

Evaluating Competent Authority: **The Netherlands**

Date: 12/04/2018

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CONCLUSION

The outcome of the assessment for the biocidal product family 'Teat disinfectants biocidal product family of CVAS' is specified in the BPC opinion following discussions at the BPC-23 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

1. ASSESSMENT REPORT

1.1 Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
TEAT DISINFECTANTS BIOCIDAL PRODUCT FAMILY OF CVAS	European Union

1.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	CVAS Development GmbH
	Address	Dr. Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Pre-submission phase started on	Date of submission: 27 February 2015 Notification of MSCAs and COM: 18 March 2015	
Pre-submission phase concluded on	End of pre-consultation: 17 April 2015 Letter of confirmation: 12 May 2015	
Authorisation number	To be determined	
Date of the authorisation	To be determined	
Expiry date of the authorisation	To be determined	

1.1.1.3 Manufacturers of the products of the family

Name of manufacturer	Calvatis GmbH
Address of manufacturer	Dr. Albert Reimann Str. 16a, 68526 Ladenburg, Germany
Location of manufacturing sites	Dr. Albert Reimann Str. 16a, 68526 Ladenburg, Germany

Name of manufacturer	Arthur Schopf Hygiene GmbH & Co. KG
Address of manufacturer	Pfaffensteinstr. 1, 83115 Neubeuern, Germany
Location of manufacturing sites	Pfaffensteinstr. 1, 83115 Neubeuern, Germany

1.1.1.4 Manufacturers of the active substances

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178 Santiago Chile
Location of manufacturing	S.C.M. Cosayach Cala Cala

sites	Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin N° 499 Iquique Chile
Location of manufacturing sites	Lagunas mine Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290 Piso 4, Las Condes Santiago Chile
Location of manufacturing sites	Nueva Victoria plant Pedro de Valdivia plant Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd/Kanto Natural Gas Development Co., Ltd
Address of manufacturer	Kanto Natural Gas Development Co., Ltd 661 Mobara, Mobara City, Chiba 297-8550, Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, Chiba, 299-4205 Japan

Technical equivalence dossier has been submitted 1 June 2015 (R4BP case number: BC-VC017566-38), Decision number: TAP-D-1175984-11-00/F Asset number: EU-0012395-0000. Chiba plant, Japan, was confirmed to be equivalent by ECHA on 23 October 2015.

Active substance	PVP-iodine
Name of manufacturer	Norkem Limited
Address of manufacturer	Norkem House, Bexton Lane, Knutsford, Cheshire, WA 16 9FB, United Kingdom
Location of manufacturing sites	Norkem House, Bexton Lane, Knutsford, Cheshire, WA 16 9FB, United Kingdom

Norkem certify to use iodine from the reference source Cosayach Nitratos S.A. for the manufacture of the PVP-iodine iodophor.

1.1.2 Product (family) composition and formulation

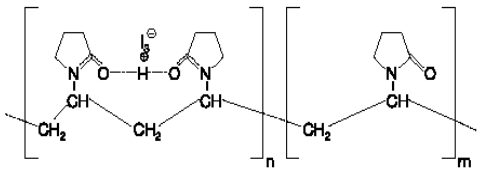
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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 ☒

1.1.2.1 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	min. 995 g/kg, manufactured to the specification of European Pharmacopoeia (*Ph. Eur.*)
Structural formula	I-I

Main constituent(s)	
ISO name	Polyvinylpyrrolidone iodine Synonym: PVP-iodine
IUPAC or EC name	Polyvinylpyrrolidone iodine
EC number	-
CAS number	25655-41-8
Index number in Annex VI of CLP	-
Minimum purity / content	Iodine contained in PVP-iodine min. 995 g/kg, iodine manufactured to the specification of European Pharmacopoeia (*Ph. Eur.*)
Structural formula	

NOTE	Iodine is formulated as PVP-iodine which is also often referred to as iodophor type 2. PVP and also the alcohol ethoxylates are used to bring iodine into the formulation in a soluble form. In line with the identity chapter of the CAR, (available) iodine is considered as the active substance. However, as iodine and PVP-iodine are often referred to as individual active substances, both are listed here under the "Identity of the active substance" chapter.

Iodine is the active substance for each family member. The family includes iodine in the form of two types of complexes (iodophores), PVP-iodine (type 2) and surfactant stabilised iodine (type 1).

Total iodine calculations
According to the Ph. Eur. specification, PVP-iodine consists of 9-12% iodine and max. 6% iodide by mass. The elemental iodine concentration is therefore 18% of the PVP-iodine concentration (worst-case assumption). However, the applicant has provided evidence that the iodide content in PVP-iodine does not exceed 4%. Therefore, the worst-case is refined and the total iodine content is calculated using 16% instead (please refer to the confidential annex for further information).

The stabiliser potassium iodide (KI), consists of 76.45% iodide by mass (M(I)/M(KI) = 126.9 g mol^{-1}/166 g mol^{-1}).

The total (elemental) iodine concentrations for meta SPC1-6 are calculated as:
16%xPVP-iodine concentration.

For meta SPC7, 8 and 9:
Available iodine content + 76.45% potassium iodide

1.1.2.2 Candidate(s) for substitution

The active substances iodine and polyvinylpyrrolidone iodine are not candidates for substitution.

Qualitative and quantitative information on the composition of the biocidal product family

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Iodine (available iodine)	Iodine	Active substance	7553-56-2	231-442-4	0.14	0.54
• In the form of pure iodine	Iodine	Active substance	7553-56-2	231-442-4	0	0.54
or						
• In the form of PVP-iodine, i.e. iodophor type-2 containing max. 12% available iodine	Polyvinyl-pyrrolidone iodine	Active substance	25655-41-8	-	0	4.16
Acetic acid	Acetic acid	Non-active substance	64-19-7	200-580-7	0	0.33

The above table provides information on the active substances iodine and PVP-iodine. Iodine is formulated into the products either as pure iodine (meta-SPCs 7, 8 and 9) or as PVP-iodine containing max. 12% available iodine (meta-SPCs 1-6).

The full composition of the BPF is confidential and is provided in the confidential Annex of the PAR.

1.1.2.3 Information on technical equivalence

As an IRG member, CVAS is committed to using only iodine from sources approved under Regulation (EU) No 528/2012 (BPR) or demonstrated as being technically equivalent. The iodine used complies with the minimum purity of 995 g/kg iodine as set by Commission Implementing Regulation (EU) No 94/2014 approving iodine (including PVP-iodine) as an existing active substance. All sources applied for are approved. For details please refer to the respective paragraph on manufacturers.

RMS remark
All iodine sources applied for are included in the list of approved sources.

1.1.2.4 Information on the substance(s) of concern

IUPAC name or other accepted chemical name	Acetic acid
EC number	200-580-7
CAS number	64-19-7
Concentration (minimum and maximum, g/kg or g/l)	0.0% – 0.33% in BPF (pure substance level)

Classification and Labelling according to Regulation (EC) No 1272/2008:	Acetic acid …% Index no: 607-002-00-6 H226, H314 Skin Corr. 1A; H314: C ≥ 90 % Skin Corr. 1B; H314: 25 % ≤ C < 90 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 %
Classification and Labelling according to the Directive 67/548/EEC	Acetic acid …% Index no: 607-002-00-6 R10; R35 C; R35: C ≥ 90 % C; R34: 25 % ≤ C < 90 % Xi; R36/38: 10 % ≤ C < 25 %
Relevant toxicological/ecotoxicological information	See SCOEL/SUM/98, June 2012
Other grounds for concern[1]	SCOEL value available: SCOEL/SUM/98, June 2012 8-hour TWA: 10 ppm (25 mg/m3) STEL (15-min): 20 ppm (50 mg/m3)

1.1.2.5 Type of formulation

Any other liquid (AL)

1.1.3 Hazard and precautionary statements

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

Product family

Classification	
Hazard category	Meta-SPCs 2-4 and meta-SPCs 7-9 : Aquatic chronic, category 3 Meta-SPC 1, meta-SPC 5, meta-SPC 6: no classification
Hazard statement	Meta-SPCs 2-4 and meta-SPCs 7-9: H412, Harmful to aquatic life with long lasting effects Meta-SPC 1, meta-SPC 5, meta-SPC 6: none
Labelling	
Signal words	No signal word
Hazard statements	Meta-SPCs 2-4 and meta-SPCs 7-9: H412, Harmful to aquatic life with long lasting effects Meta-SPC 1, meta-SPC 5, meta-SPC 6: none

[1] Please include PBT, vPvB, POP and ED properties, if relevant.

Precautionary statements	Meta-SPCs 2-4: P101 – If medical advice is needed, have product container or label at hand. P102 – Keep out of reach of children. P273 – Avoid release to the environment. P501 – Dispose of contents/containers in accordance with local/regional/national/international regulation. Meta-SPC 1, meta-SPC 5 and meta-SPC 6: P101 – If medical advice is needed, have product container or label at hand. P102 – Keep out of reach of children. Meta-SPCs 7-9: P273 – Avoid release to the environment. P501 – Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-

For precautionary reasons, the "Dip es" products (meta-SPCs 1-6) bear the P-statements P101 and P102.
The "calgodip D" products (meta-SPC 7, meta-SPC 8 and meta-SPC 9) are similar in composition to a product which has been tested for its primary eye irritancy and was found not to have eye irritant properties. Consequently, the "calgodip D" products do not meet the classification criteria for local effects on the eyes (i.e. "no classification").

1.1.4 Authorised uses

1.1.4.1 Use description

Below the different uses are indicated for which the products are authorised and in which meta-SPC the use is applicable.

Table 1. Use # 1.1 - Teat disinfection of milkable animals: Pre-milking teat disinfection by manual foaming (applicable to meta-SPC 6)

Product Type	PT3
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: Teat disinfection product for milkable animals (dairy cows) for use before milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Pre-milking application: 2 – 3x/day (before each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.2 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids. Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection. Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant. Leave the product on the teats for at least 60 seconds. Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

1.1.4.3 Use-specific risk mitigation measures

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 2. Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping (applicable to meta-SPCs 1-5 and meta-SPCs 7-9)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.7 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the dip cup on top. Avoid discharge of surplus fluids. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant. Refill the cup of the dipping unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed. Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

1.1.4.8 Use-specific risk mitigation measures

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.

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 3. Use # 1.3 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming (applicable to meta-SPC 6, meta-SPC 7 and meta-SPC 9)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant

Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.12 Use-specific instructions for use

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

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.

After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

1.1.4.13 Use-specific risk mitigation measures

metaSPC 7 & 9: 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.

metaSPC6: 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

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 4. Use # 1.4 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer (applicable to meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.17 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended. Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the top of the trigger sprayer on it. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the trigger sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant. Refill the reservoir of the trigger sprayer with fresh disinfectant as needed. Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

1.1.4.18 Use-specific risk mitigation measures

Meta–SPC 4 and 7: Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying using a trigger sprayer. Avoid working in a spray mist. Meta–SPC 5: Avoid working in a spray mist. Meta-SPC 9: Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coverall and chemical resistant boots during post-milking teat disinfection by manual spraying using a trigger sprayer. Avoid working in a spray mist. 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.

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 5. Use # 1.5 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer (applicable to meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type	PT3

Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.22 Use-specific instructions for use

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

Open a can containing the RTU product assuming 5 mL product per cow and insert a sucking lance of the electronic sprayer. Avoid discharge of surplus fluids.

Clean carefully the teats by wiping with a single service paper towel/cloth before milking.

After milking, spray the disinfectant on the teats using the electronic sprayer making sure that about 3 cm of the teat around the streak canal are covered with the disinfectant.

Replace the empty can by a new can containing the RTU product as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

1.1.4.23 Use-specific risk mitigation measures

Meta-SPC 4 and 7: Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during post-milking teat disinfection by manual spraying using an electronic sprayer. Avoid working in a spray mist.

Meta-SPC 5: Avoid working in a spray mist.

Meta-SPC 9: Use chemical resistant gloves (glove material to be specified by the authorisation holder within the product information), coverall and chemical resistant boots during post-milking teat disinfection by manual spraying using an electronic sprayer. Avoid working in a spray mist.

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.

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 6. Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping (applicable to meta-SPCs 1-5 and meta-SPCs 7-9)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated dipping
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.27 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. Open a can containing the RTU product and insert a suction tube of the automated dipping-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

1.1.4.28 Use-specific risk mitigation measures

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.

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 7. Use # 1.7 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming (applicable to meta-SPC 6, meta-SPC 7 and meta-SPC 9)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Automated foaming
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.32 Use-specific instructions for use

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

Open a can containing the RTU product and insert a suction tube of the automated foaming-system. Avoid discharge of surplus fluids.

After milking, the vacuum is shut off and the teat disinfectant is injected into a manifold on the clawpiece. The teats are coated with ca. 5 mL of foam when the teat foam cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated foaming-system is thoroughly rinsed with water and blown out with compressed air.

In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.

Afterwards, the milking system is ready for the next milking event.

The whole process is automated.

1.1.4.33 Use-specific risk mitigation measures

metaSPC 7 & 9: 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.

metaSPC6: 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

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 8. Use # 1.8 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot (applicable to meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type	PT3
Where relevant, an exact description of the authorised use	not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor:Teat disinfection product for milkable animals (dairy cows) for use after milking
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.37 Use-specific instructions for use

The product must be brought to a temperature above 20°C before use. Open a can containing the RTU product and insert a suction tube of the robotic milking device. Avoid discharge of surplus fluids. The teats are cleaned by robot with automatic brushes. After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm. Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment. Rinsing of the sprayer is automatic.

1.1.4.38 Use-specific risk mitigation measures

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.

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

See general directions for use

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

See general directions for use

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

See general directions for use

Table 9. Use # 1.9 – Teat disinfection of milkable animals: Pre- and post-milking teat disinfection by manual foaming (applicable to meta-SPC 6)

Product Type	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Effective against bacteria and yeasts
Field(s) of use	Indoor: teat disinfection for milkable animals (dairy cows) for use before and after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Pre- and post-milking application: 4-6 times per day (before and after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.1.4.42 Use-specific instructions for use

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

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the reservoir with the RTU product assuming 5 mL product per cow and screw the foam cup on top. Avoid discharge of surplus fluids.

Clean the teats carefully by wiping with a single service paper towel/cloth before pre-milking disinfection.

Before milking, squeeze the reservoir and put the foam cup over each teat from below making sure that about 3 cm of the teat are immersed into the disinfectant.

Leave the product on the teats for at least 60 seconds.

Clean the teats carefully by wiping with a cloth immediately before milking. After milking, repeat the disinfection by foaming as described above.

Refill the cup of the foaming unit with fresh disinfectant by squeezing the reservoir as needed. Refill the reservoir with fresh disinfectant as needed.

Leave the product on the teats until next milking. Keep the animals standing for at least 5 minutes after treatment.
After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

1.1.4.43 Use-specific risk mitigation measures

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

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

See general directions for use

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

See general directions for use

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

See general directions for use

1.1.5 General directions for use

1.1.5.1 Instructions for use

See use specific instructions for use.

1.1.5.2 Risk mitigation measures

See use-specific risk mitigation measures.

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

Description of first aid measures
After inhalation: Supply fresh air; consult doctor in case of symptoms.
After skin contact: Instantly wash with water and soap and rinse thoroughly.
After eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).
After swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

If medical advice is needed, have product container or label at hand.

Stability and reactivity
Reactivity: No dangerous reactions known.
Chemical stability: The product is chemically stable under normal surroundings terms (ambient temperature).
Possibility of hazardous reactions: By designated use no dangerous reactions are to be expected.
Conditions to avoid: Not determined.
Incompatible materials: Not determined.
Hazardous decomposition products: No dangerous decomposition products known.

Accidental release measures
Personal precautions, protective equipment and emergency procedures: Wear protective clothing.
Ensure adequate ventilation.
Keep ignition sources away - Do not smoke.
Environmental precautions: Do not allow to enter drainage system, surface or ground water.
Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

1.1.5.4 Instructions for safe disposal of the product and its packaging

Waste treatment methods: Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Must be specially treated under adherence to official regulations.

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

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

Shelf-life at ambient temperature: 18 months for meta-SPC 1, 2, 3, 4, 5 and 6 24 months for meta-SPC 7, 8 and 9 Products need to be protected from frost, stored at temperatures not exceeding above 30°C and away from direct sunlight.

1.1.6 Other information

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1.1.7 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)**
Jerrycan	5 – 60 kg	HDPE, opaque	Screw caps (HDPE) Seals (PE)	Professional users	yes
Drum	60 – 200 kg	HDPE, Opaque	Screw caps (HDPE) Seals (PE)	Professional users	yes
IBC	600 - 1000 kg	HDPE, Opaque	Screw caps (HDPE) Seals (PE)	Professional users	yes

1.1.8 Documentation

1.1.8.1 Data submitted in relation to product application

Concerning the active substances iodine and PVP-iodine, no new data is submitted with this biocidal product family dossier.

Concerning product data in support of this biocidal product family dossier, please refer to reference list provided in the Annex.

1.1.8.2 Access to documentation

CVAS Development GmbH is a full member of the Iodine Registration Group (IRG) who is the applicant of the BPD iodine (incl. PVP-iodine) dossier in PTs 3, 4 and 22. As a review programme participant, CVAS Development GmbH has data access to the complete iodine dossier. The "Declaration on Ownership of Data and Access Rights", the letter of access granted by the IRG, is attached to section 13 of the IUCLID file.

1.1.8.3 Similar conditions of use

The biocidal product family "Teat disinfectants biocidal product family of CVAS" is deemed to be eligible for Union authorisation according to the communication of ECHA of 12 May 2015 (Communication number D(2015)1856).

1.2 Assessment of the biocidal product (family)

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

The uses below are the ones applied for by the applicant. In the original application pre-milking and pre- and post-milking was claimed for more meta-SPC's and for more application methods than foaming. In addition shorter contact times were stated. Part of the original assessment is still shown in the following chapters.

See 1.1.4 for the authorised uses (after assessment of the dossier).

Use # 1 – Teat disinfection of milkable animals

Table 1. Intended use # 1.1 – Teat disinfection of milkable animals: Pre-milking teat disinfection by manual foaming (meta-SPC 6)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: Teat disinfection product for milkable animals (cows) for use before milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Pre-milking application: 2 – 3x/day (before each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 2. Intended use # 1.2 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping (meta-SPCs 1-5 and meta-SPCs 7-9)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 3. Intended use # 1.3 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming (meta-SPC 6)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 4. Intended use # 1.4 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer (meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 5. Intended use # 1.5 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer (meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Application rates: Cows 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 6. Intended use # 1.6 – Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping (meta-SPCs 1-5and meta-SPCs 7-9)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking

Application method(s)	Automated dipping
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 7. Intended use # 1.7 – Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming (meta-SPC 6)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use after milking
Application method(s)	Automated foaming
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 8. Intended use # 1.8 – Teat disinfection of milkable animals: post-milking teat disinfection by automated spraying by robot (meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: Teat disinfection product for milkable animals (cows) for use after milking

Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Post-milking application: 2 – 3x/day (after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

Table 9. Intended use # 1.9 – Teat disinfection of milkable animals: Pre- and post-milking teat disinfection by manual foaming (meta-SPC 6)

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Effective against bacteria and yeasts
Field of use	Indoor: teat disinfection for milkable animals (dairy cows) for use before and after milking
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows: 5 mL/treatment Application frequency: Pre- and post-milking application: 4 – 6 times per day (before and after each milking)
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	Please see the relevant section.

1.2.2 Physical, chemical and technical properties

A dossier on physical and chemical properties is available for all individual products within the family. Where read-across is requested, this is mentioned in the column 'reference'.

The eCA has added remarks within the table where deemed necessary. The products tested and the meta-SPCs they belong to are summarised in the following table:

Meta-SPC 1	Dip es barriere
Meta-SPC 2	Dip es Io-film
Meta-SPC 3	Dip es barriere S Dip es barriere RS
Meta-SPC 4	Dip es silver
Meta-SPC 5	Dip es SF
Meta-SPC 6	Dip es Io-foam
Meta-SPC 7	calgodip D 1200
Meta-SPC 8	calgodip D 3000 film calgodip D 5000
Meta-SPC 9	calgodip D 3000

All products are ready to use liquids, not diluted prior to use.

Property	**Guideline and Method**	**Purity of the test substance % (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual assessment during accel. storage stability tests.	All products of the BPF <u>Iodine conc.</u> Available: 0.14-0.54 Total: 0.19-0.92	Liquid viscous	Affolter, O. (2015) Report no. 15031706N978 Affolter, O. (2015) Report no. 15031708N978 Manka, S. (2015) Report no. Mo5242 Affolter, O. (2015) Report no. 15031703N978 Manka, S. (2015) Report no. Mo5242 Manka, S. (2015) Report no. Mo5242 Manka, S. (2015) Report no. Mo5242
eCA comment Acceptable. All products within the family are liquids.				
Colour at 20 °C and 101.3 kPa	Visual assessment during accel. storage stability tests.	All products of the BPF <u>Iodine conc.</u> Available: 0.14-0.54 Total: 0.19-0.92	Colour of the different products may vary from dark brown over black red to red orange or ruby red.	
eCA comment				

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Acceptable. The family contains products with and without additional dyes. Therefore, colours may differ, but generally are in the range yellow to reddish black due to the effect of iodine.				Affolter, O. (2015) Report no. 15031613N978
Odour at 20 °C and 101.3 kPa	Olfactory inspection during accel. storage stability tests.	All products of the BPF <u>Iodine conc.</u> Available: 0.14-0.54 Total: 0.19-0.92	Slight iodine odour	Affolter, O. (2015) Report no. 15031611N978 Affolter, O. (2015) Report no. 15031610N978 Affolter, O. (2015) Report no. 15031612N978
Acidity/alkalinity	pH value: CIPAC MT75.3 Acidity: CIPAC MT191	Dip es barriere RS <u>Iodine conc.</u> Available: 0.50 Total: 0.67	pH = 5.17 (at 25 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031706N978
		Dip es barriere S <u>Iodine conc.</u> Available: 0.30 Total: 0.40	pH = 5.61 (at 25 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031708N978
		Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19	pH = 4.3 (at 21.2 °C) Acidity: n.a.; 4 < pH < 10	Manka, S. (2015) Report no. Mo5242
		Dip es lo-film <u>Iodine conc.</u> Available: 0.30 Total: 0.40	pH = 5.35 (at 25.0 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031703N978
		Dip es silver <u>Iodine conc.</u> Available: 0.30 Total: 0.40	pH = 4.2 (at 20.9 °C) Acidity: n.a.; 4 < pH < 10	Manka, S. (2015) Report no. Mo5242
		Dip es SF <u>Iodine conc.</u> Available: 0.14 Total: 0.19	pH = 4.3 (at 20.6 °C) Acidity: n.a.; 4 < pH < 10	Manka, S. (2015) Report no. Mo5242
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	pH = 4.4 (at 21.2 °C) Acidity: n.a.; 4 < pH < 10	Manka, S. (2015) Report no. Mo5242
		calgodip D 1200	pH = 5.66 (at 25 °C)	Affolter, O. (2015) Report no.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Iodine conc. Available: 0.14 Total: 0.29	Acidity: n.a.; 4 < pH < 10	15031613N978
		calgodip D 3000 Iodine conc. Available: 0.34 Total: 0.72	pH = 5.47 (at 25 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031611N978
		calgodip D 3000 Film Iodine conc. Available: 0.34 Total: 0.72	pH = 5.17 (at 25 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031610N978
		calgodip D 5000 Iodine conc. Available: 0.54 Total: 0.92	pH = 5.22 (at 25 °C) Acidity: n.a.; 4 < pH < 10	Affolter, O. (2015) Report no. 15031612N978
eCA comment The pH of the products within the family is limited to the range 4 to 6 (see section 3.6, confidential information).				
Relative density / bulk density	EU Method A.3 (Relative Density)	Dip es barriere Iodine conc. Available: 0.14 Total: 0.19	Relative Density: D_4^{20} = 1.026	Manka, S. (2015) Report no. Mo5242
		Dip es silver Iodine conc. Available: 0.30 Total: 0.40	Relative Density: D_4^{20} = 1.045	Manka, S. (2015) Report no. Mo5242
		Dip es SF Iodine conc. Available: 0.14 Total: 0.19	Relative Density: D_4^{20} = 1.021	Manka, S. (2015) Report no. Mo5242
		Dip es Io-foam Iodine conc. Available: 0.14 Total: 0.19	Relative Density: D_4^{20} = 1.027	Manka, S. (2015) Report no. Mo5242
	OECD Guideline 109 (Density of Liquids and Solids); EU Method A.3 (Relative Density)	Dip es barriere RS Iodine conc. Available: 0.50 Total: 0.67	Relative Density: D_4^{20} = 1.0091	Affolter, O. (2015) Report no. 15031706N978
		Dip es barriere S	Relative Density: D_4^{20} = 1.0088	Affolter, O. (2015) Report no.

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Iodine conc. Available: 0.30 Total: 0.40		15031708N978
		Dip es lo-film Iodine conc. Available: 0.30 Total: 0.40	Relative Density: D_4^{20} = 1.0211	Affolter, O. (2015) Report no. 15031703N978
		calgodip D 1200 Iodine conc. Available: 0.14 Total: 0.29	Relative Density: D_4^{20} = 1.0258	Affolter, O. (2015) Report no. 15031613N978
		calgodip D 3000 Iodine conc. Available: 0.34 Total: 0.72	Relative Density: D_4^{20} = 1.0301	Affolter, O. (2015) Report no. 15031611N978
		calgodip D 3000 Film Iodine conc. Available: 0.34 Total: 0.72	Relative Density: D_4^{20} = 1.0376	Affolter, O. (2015) Report no. 15031610N978
		calgodip D 5000 Iodine conc. Available: 0.54 Total: 0.92	Relative Density: D_4^{20} = 1.0364	Affolter, O. (2015) Report no. 15031612N978
eCA comment Acceptable. The density of the products in the family is within the range of 1.0 to 1.05. No potential products are expected to fall outside this range.				
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (modified, see eCA remark)	Dip es barriere RS Iodine conc. Available: 0.50 Total: 0.67	Product and packaging (1 L HDPE): Stable at 30 °C for 18 weeks Iodine content Initial: 0.524% 9w: 0.483% 92.2% of initial iodine 18w: 0.443% 84.5% of initial iodine Total iodine (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a Appearance	Affolter, O. (2015) Report no. 15031706N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Initial: black brown (RAL 8022) viscous liquid 9w: no change 18w: black red (RAL 3007) viscous liquid Packaging Initial: n/a 9w: n/a 18w: n/a pH (CIPAC MT75.3) Initial: 5.17 9w: 3.58 18w: 3.10 Viscosity (CIPAC MT192) Dynamic viscosity at 20 °C Initial: 709-5027 cP at 100-10 rpm, spindle no 63 9w: 713-5093 cP at 100-10 rpm, spindle no 63 18w: 678-4377 cP at 100-10 rpm, spindle no 63 Kinematic viscosity at 20 °C Initial: 703-4982 cSt at 100-10 rpm, spindle no 63 9w: 707-5048 cSt at 100-10 rpm, spindle no 63 18w: 672-4338 cSt at 100-10 rpm, spindle no 63 Dynamic viscosity at 40 °C Initial: 641-4607 cP at 100-10 rpm, spindle no 63 9w: 656-4350 cP at 100-10 rpm, spindle no 63 18w: 912-5273 cP at 100-10 rpm, spindle no 63	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Kinematic viscosity at 40 °C Initial: 635-4566 cSt at 100-10 rpm, spindle no 63 9w: 650-4311 cSt at 100-10 rpm, spindle no 63 18w: 904-5226 cSt at 100-10 rpm, spindle no 63 Density Initial: 1.0090 g/cm^3 9w: n/a 18w: n/a Relative Density Initial: D= 1.011 (is not included in study report but calculated by SCC)	
		Dip es barriere S Iodine conc. Available: 0.30 Total: 0.40	Product and packaging (1 L HDPE): Stable at 30 °C for 9 weeks Iodine content Initial: 0.296% 9w: 0.292% 98.6% of initial iodine 18w: n/a Total iodine (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a Appearance Initial: black brown (RAL 8022) viscous liquid 9w: no change 18w: n/a Packaging Initial: n/a 9w: n/a 18w: n/a pH (CIPAC MT75.3)	Affolter, O. (2015) Report no. 15031708N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Initial: 5.61 9w: n/a 18w: n/a Viscosity (CIPAC MT192) Dynamic viscosity at 20 °C Initial: 536-3727 cP at 100-10 rpm, spindle no 63 9w: n/a 18w: n/a Kinematic viscosity at 20 °C Initial: 531-3695 cSt at 100-10 rpm, spindle no 63 9w: n/a 18w: n/a Dynamic viscosity at 40 °C Initial: 465-3410 cP at 100-10 rpm, spindle no 63 9w: n/a 18w: n/a Kinematic viscosity at 40 °C Initial: 461-3381 cSt at 100-10 rpm, spindle no 63 9w: n/a 18w: n/a Density Initial: 1.0087 g/cm^3 9w: n/a 18w: n/a Relative Density Initial: D=1.015 (is not included in study report but calculated by SCC)	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<u>Product and packaging</u> (1 L HDPE): Stable at 40 °C for 2 weeks <u>Iodine content</u> Initial: 0.1564% 2w : 0.1324% (84.7% of initial iodine) <u>Total iodine</u> (iodine and iodide) Initial: 0.1796% 2w: 0.1700% (94.7% of initial iodine) <u>Appearance</u> Initial: Homogeneous, turbid rust brown liquid 2w: No change <u>Packaging</u> Initial: Sealed, no leaks 2w: No change <u>pH</u> (CIPAC MT75.3) Initial: 4.3 4w: 3.4 <u>Viscosity</u> (CIPAC MT192) Initial: 20.28 – 291/84 mPa.s at 181 – 56 min^{-1} 2w: 23.40 – 322.56 mPa.s at 181 – 56 min^{-1} <u>Relative density</u> Initial: D_4^{20} = 1.026 2w: D_4^{20} = 1.029	Manka, S. (2015) Report no. Mo5242
		eCA remark (pH) The study was performed for 2 weeks at 40°C, but the report states the pH was determined after 4 weeks. This is expected to be a typo.		
		Dip es lo-film <u>Iodine conc.</u> Available: 0.30 Total: 0.40	<u>Product and packaging</u> (1L HDPE): Stable at 30 °C for 9 weeks plus further 9 weeks at 20±5 °C <u>Iodine content</u> Initial: 0.300% 9w: 0.249%	Affolter, O. (2015) Report no. 15031703N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			82.9% of initial iodine 18w: 0.236% 78.8% of initial iodine Total iodine (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a Appearance Initial: black red (RAL 3007) viscous liquid 9w: no change 18w: brown red (RAL 3011) viscous liquid Packaging Initial: n/a 9w: n/a 18w: n/a pH (CIPAC MT75.3) Initial: 5.35 9w: n/a 18w: 3.96 Viscosity (CIPAC MT192) Dynamic viscosity at 20 °C Initial:526-3817 cP at 100-10 rpm, spindle no 63 9w: n/a 18w: 1038-7673 cP at 60-5 rpm, spindle no 63 Kinematic viscosity at 20 °C Initial: 514-3738 cSt at 100-10 rpm, spindle no 63 9w: n/a 18w: 1017-7515 cSt at 60-5 rpm, spindle no 63 Dynamic viscosity at 40 °C Initial: 630-4220 cP at 100-10 rpm, spindle	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			no 63 9w: n/a 18w: 691-4057 cP at 100-10 rpm, spindle no 63 <u>Kinematic viscosity at 40 °C</u> Initial: 617-4133 cSt at 100-10 rpm, spindle no 63 9w: n/a 18w: 676-3973 cSt at 100-10 rpm, spindle no 63 <u>Density</u> Initial: 1.0211 g/cm^3 9w: n/a 18w: n/a <u>Relative Density</u> Initial: D_4^{20}= 1.002 (is not included in study report but calculated by SCC)	
		Dip es silver <u>Iodine conc.</u> Available: 0.30 Total: 0.40	<u>Product and packaging</u> (1L HDPE): Stable at 40 °C for 4 weeks <u>Iodine content</u> Initial: 0.3117% 2w: 0.2984% 95.7% of initial iodine 4w: 0.2589% 83.1% of initial iodine <u>Total iodine</u> (iodine and iodide) Initial: 0.3966% 2w: 0.4098% 103.3% if initial total iodine 4w: 0.3887% 98.0% of initial total iodine <u>Appearance</u> Initial: Homogeneous, turbid rust brown liquid 2w: no change	Manka, S. (2015) Report no. Mo5242

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			4w: no change Packaging Initial: sealed, no leaks 2w: no change 4w: no change pH (CIPAC MT75.3) Initial: 4.2 2w: 3.7–3.8 4w: 3.6 Viscosity (CIPAC MT192) Initial: 8.16-53.76 mPa.s at 181-5.6min^{-1} 2w: 8.04-57.60 mPa.s at 181-5.6min^{-1} 4w: 7.92-49.92 mPa.s at 181-5.6min^{-1} Relative density Initial: D_4^{20}= 1.045 2w: D_4^{20}=1.044 4w: D_4^{20}=1.045	
		Dip es SF Iodine conc. Available: 0.14 Total: 0.19	Product and packaging (1L HDPE): Stable at 40 °C for 4 weeks Iodine content Initial: 0.1579% 4w: 0.1502% 95% of initial iodine Total iodine (iodine and iodide) Initial: 0.1836% 4w: 0.1816% 98.9% of initial total iodine Appearance Initial: Homogeneous, turbid rust brown liquid 4w: no change Packaging Initial: sealed, no leaks 4w: no change pH (CIPAC MT75.3) Initial: 4.3	Manka, S. (2015) Report no. Mo5242

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			4w: 3.5-3.6 <u>Viscosity</u> (CIPAC MT192) Initial: <2-3.84 mPa.s at 181-5.6min^{-1} 4w: <2 mPa.s at 181-5.6min^{-1} <u>Relative density</u> Initial: D_4^{20}= 1.021 4w: D_4^{20}=1.020	
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<u>Product and packaging</u> (1L HDPE): Stable at 40 °C for 4 weeks <u>Iodine content</u> Initial: 0.1508% 2w: 0.1514% 100.4% of initial iodine 4w: 0.1291% 85.6% of initial iodine <u>Total iodine</u> (iodine and iodide) Initial: 0.1828% 2w: 0.1811% 99.1% if initial total iodine 4w: 0.1830% 100.1% of initial total iodine <u>Appearance</u> Initial: Homogeneous, turbid rust brown liquid 2w: no change 4w: no change <u>Packaging</u> Initial: sealed, no leaks 2w: no change 4w: no change <u>pH</u> (CIPAC MT75.3) Initial: 4.3-4.4 2w: 4.1 4w: 3.7-3.8 <u>Viscosity</u> (CIPAC MT192) Initial:<2-3.84	Manka, S. (2015) Report no. Mo5242

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			mPa.s at 181-5.6min^{-1} 2w: <2 mPa.s at 181-5.6min^{-1} 4w: <2 mPa.s at 181-5.6min^{-1} <u>Relative density</u> Initial: D_4^{20}= 1.027 2w: D_4^{20}=1.027 4w: D_4^{20}=1.026	
		calgodip D 1200 <u>Iodine conc.</u> Available: 0.14 Total: 0.29	<u>Product and packaging</u> (1L HDPE): Stable at 30 °C for 18 weeks <u>Iodine content</u> Initial: 0.145% 9w: 0.140% 96.4% of initial iodine 18w: 0.134% 92.6% of initial iodine <u>Total iodine</u> (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a <u>Appearance</u> Initial: red orange (RAL 2001) liquid 9w: no change 18w: deep orange (RAL 2011) liquid <u>Packaging</u> Initial: n/a 9w: n/a 18w: n/a <u>pH</u> (CIPAC MT75.3) Initial: 5.66 9w: n/a 18w: 5.59 <u>Viscosity</u> (CIPAC MT192) <u>Dynamic viscosity at 20 °C</u> Initial:<5 cP at 100 rpm, spindle no 61	Affolter, O. (2015) Report no. 15031613N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			9W: n/a 18w: n/a <u>Density</u> Initial: 1.0258 g/cm^3 9w: n/a 18w: n/a <u>Relative Density</u> Initial: D= 1.028 (is not included in study report but calculated by SCC)	
		calgodip D 3000 <u>Iodine conc.</u> Available: 0.34 Total: 0.72	<u>Product and packaging</u> (1L HDPE): Stable at 30 °C for 18 weeks <u>Iodine content</u> Initial: 0.345% 9w: 0.334% 96.8% of initial iodine 18w: 0.322% 93.4% of initial iodine <u>Total iodine</u> (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a <u>Appearance</u> Initial: ruby red (RAL 3003) slightly viscous liquid 9w: no change 18w: vermilion (RAL 2002) slightly viscous liquid <u>Packaging</u> Initial: n/a 9w: n/a 18w: n/a <u>pH</u> (CIPAC MT75.3) Initial: 5.47 9w: n/a 18w: 5.39 <u>Viscosity</u> (CIPAC MT192)	Affolter, O. (2015) Report no. 15031611N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Dynamic viscosity at 20 °C Initial:<5 cP at 100 rpm, spindle no 61 9W: n/a 18w: n/a Density Initial: 1.0301 g/cm^3 9w: n/a 18w: n/a Relative Density Initial: D= 1.032 (is not included in study report but calculated by SCC)	
		calgodip D 3000 Film Iodine conc. Available: 0.34 Total: 0.72	Product and packaging (1L HDPE): Stable at 30 °C for 18 weeks Iodine content Initial: 0.338% 9w: 0.322% 95.2% of initial iodine 18w: 0.304% 89.9% of initial iodine Total iodine (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a Appearance Initial: ruby red (RAL 3003) viscous liquid 9w: no change 18w: red orange (RAL 2001) viscous liquid Packaging Initial: n/a 9w: n/a 18w: n/a pH (CIPAC MT75.3) Initial: 5.17	Affolter, O. (2015) Report no. 15031610N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			9w: n/a 18w: 5.08 <u>Viscosity</u> (CIPAC MT192) <u>Dynamic viscosity at 20 °C</u> Initial:1230-19520 cP at 50-2 rpm, spindle no 63 9w: n/a 18w: 1273-17980 cP at 50-2 rpm, spindle no 63 <u>Kinematic viscosity at 20 °C</u> Initial: 1185-18813 cSt at 50-2 rpm, spindle no 63 9w: n/a 18w: 1227-17328 cSt at 50-2 rpm, spindle no 63 <u>Density</u> Initial: 1.0376 g/cm^3 9w: n/a 18w: n/a <u>Relative Density</u> Initial: D= 1.039 (is not included in study report but calculated by SCC)	
		calgodip D 5000 <u>Iodine conc.</u> Available: 0.54 Total: 0.92	<u>Product and packaging</u> (1L HDPE): Stable at 30 °C for 18 weeks <u>Iodine content</u> Initial: 0.566% 9w: 0.561% 99.1% of initial iodine 18w: 0.534% 94.4% of initial iodine <u>Total iodine</u> (iodine and iodide) Initial: n/a 9w: n/a 18w: n/a	Affolter, O. (2015) Report no. 15031612N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Appearance Initial: wine red (RAL 3005) viscous liquid 9w: no change 18w: ruby red (RAL 3003) viscous liquid Packaging Initial: n/a 9w: n/a 18w: n/a pH (CIPAC MT75.3) Initial: 5.22 9w: n/a 18w: 5.15 Viscosity (CIPAC MT192) Dynamic viscosity at 20 °C Initial:107-341 cP at 50-6 rpm, spindle no 61 9w: n/a 18w: 62-143 cP at 50-6 rpm, spindle no 61 Kinematic viscosity at 20 °C Initial: 103-329 cSt at 50-6 rpm, spindle no 61 9w: n/a 18w: 60-138 cSt at 50-6 rpm, spindle no 61 Density Initial: 1.0363 g/cm^3 9w: n/a 18w: n/a Relative Density Initial: D= 1.038 (is not included in study report but calculated by SCC)	
eCA remark Products are generally not stable when stored under accelerated conditions with the exception of				

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
the Calgodip products of meta SPC 7, 8 and 9. It should be noted that not all studies were performed following the CIPAC MT46.3 protocol. The test durations were modified (halved) in some cases. This does not affect the reliability of the test, but generally does not allow extrapolation to a shelf-life of 2 years. The analytical method used for determination of the iodine content is the same as the pharmacopoeia published titration method (see analytical method section, 1.2.4) and is considered sufficiently valid for its purpose. In addition, the products tested within meta SPC 1 to 6 show a decrease in pH to below 4. The eCA considers that the products within meta 1 to 6 should not be stored at or above 30°C. For SPC 7, 8 and 9, tests were performed at 30 degrees only, which results in the same storage conditions as for meta SPCs 1 to 6.				
Storage stability test – **long term storage at ambient temperature**		Dip es barriere RS <u>Iodine conc.</u> Available: 0.50 Total: 0.67	The product is similar in composition to a tested product of the BPF.	Read-across Please refer to confidential Annex
		Dip es barriere S <u>Iodine conc.</u> Available: 0.30 Total: 0.40	The product is similar in composition to a tested product of the BPF.	Read-across Please refer to confidential Annex
		Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<u>Product and packaging</u> (in HDPE): Stable at 20 °C for 18.5 months <u>Appearance:</u> Initial: homogeneous, clear rust brown liquid, Pantone 476 C 3 months: homogeneous, clear rust brown liquid, Pantone 476 C 6 months: homogeneous, clear rust brown liquid, Pantone 476 C 12 months: homogeneous, clear rust brown liquid, Pantone 476 C 18.5 months: homogeneous, clear rust brown liquid, Pantone 476 C <u>Packaging:</u>	Manka, S. (2017) Report no. Mo5349

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Initial: Sealed, no leaks 12 months: no change 18.5 months: no change <u>pH (CIPAC MT75.3):</u> Initial: 5.4 3 months: 5.4 6 months: 5.2 12 months: 4.9 18.5 months: 4.8 <u>Viscosity</u> (CIPAC MT192) Initial: 25.68 – 337.92 mPa.s at 181 – 5.6 min^{-1} 12 months: 22.32 – 272.64 mPa.s at 181 – 5.6 min^{-1} 18.5 months: 25.92 – 353.28 mPa.s at 181 – 5.6 min^{-1} <u>Relative Density:</u> Initial: D_4^{20} = 1.025 12 months: D_4^{20} = 1.025 18.5 months: D_4^{20} = 1.023 <u>Iodide:</u> Initial: 0.0416% 3 months: 0.0325% 6 months: 0.0457% 12 months: 0.0531% 18.5 months: 0.0640% <u>Iodine:</u> Initial: 0.146% 3 months: 0.145% 6 months: 0.134% 12 months: 0.122% 18.5 months: 0.105% <u>Total iodine:</u> Initial: 0.1873% 3 months: 0.1773% 6 months: 0.1792% 12 months: 0.1754% 18.5 months: 0.1693%	
		Dip es lo-film	<u>Product and packaging</u>	Manka, S. (2017)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Iodine conc. Available: 0.30 Total: 0.40	(in HDPE): Stable at 20 °C for 18.5 months Appearance: Initial: homogeneous, clear rust brown liquid, Pantone 4975 C 3 months: homogeneous, clear rust brown liquid, Pantone 483 C 6 months: homogeneous, clear rust brown liquid, Pantone 4975C 12 months: homogeneous, clear rust brown liquid, Pantone 4975 C 18.5 months: homogeneous, clear rust brown liquid, Pantone 4975 C Packaging: Initial: Sealed, no leaks 12 months: no change 18.5 months: no change pH (CIPAC MT75.3): Initial: 5.4 3 months: 5.2 - 5.3 6 months: 4.9 12 months: 4.7 18.5 months: 4.6 – 4.7 Viscosity (CIPAC MT192) Initial: n.d.– 353.28 mPa.s at 181 – 5.6 min^{-1} 12 months: 37.08 – 314.88 mPa.s at 181 – 5.6 min^{-1} 18.5 months: n.d. – 437.76 mPa.s at 181 – 5.6 min^{-1} Relative Density: Initial: D_4^{20} = 1.030 12 months: D_4^{20} =	Report no. Mo5350

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			1.033 18.5 months: D_4^{20} = 1.035 <u>Iodide:</u> Initial: 0.1036% 3 months: 0.0985% 6 months: 0.1208% 12 months: 0.1328% 18.5 months: 0.1524% <u>Iodine:</u> Initial: 0.318% 3 months: 0.318% 6 months: 0.294% 12 months: 0.278% 18.5 months: 0.262% <u>Total iodine:</u> Initial: 0.4218% 3 months: 0.4169% 6 months: 0.4151% 12 months: 0.4104% 18.5 months: 0.4144%	
		Dip es silver <u>Iodine conc.</u> Available: 0.30 Total: 0.40	<u>Product and packaging</u> (in HDPE): Packaging: Stable at 20 °C for 18.5 months <u>Appearance:</u> Initial: homogeneous, turbid rust brown liquid, Pantone 497 C 3 months: homogeneous, turbid rust brown liquid, Pantone 483 C 6 months: homogeneous, turbid rust brown liquid, Pantone 497 C 12 months: homogeneous, turbid rust brown liquid, Pantone 497 C 18.5 months: homogeneous, turbid rust brown liquid, Pantone 497 C	Manka, S. (2017) Report no. Mo5346

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			<u>Packaging:</u> Initial: Sealed, no leaks 12 months: no change 18.5 months: no change <u>pH (CIPAC MT75.3):</u> Initial: 5.2 3 months: 5.3 - 5.4 6 months: 5.0 12 months: 4.7 18.5 months: 4.5 – 4.6 <u>Viscosity</u> (CIPAC MT192) Initial: 8.52 – 61.44 mPa.s at 181 – 5.6 min^{-1} 12 months: 8.04 – 53.76 mPa.s at 181 – 5.6 min^{-1} 18.5 months: 8.52 – 57.60 mPa.s at 181 – 5.6 min^{-1} <u>Relative Density:</u> Initial: D_4^{20} = 1.045 12 months: D_4^{20} = 1.045 18.5 months: D_4^{20} = 1.045 <u>Iodide:</u> Initial: 0.0982% 3 months: 0.0956% 6 months: 0.1145% 12 months: 0.1471% 18.5 months: 0.1539% <u>Iodine:</u> Initial: 0.310% 3 months: 0.310% 6 months: 0.281% 12 months: 0.259% 18.6 months: 0.240% <u>Total iodine:</u> Initial: 0.4083% 3 months: 0.4052% 6 months: 0.3954% 12 months: 0.4065% 18.6 months: 0.3937%	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Dip es SF <u>Iodine conc.</u> Available: 0.14 Total: 0.19	The product is similar in composition to a tested product of the BPF.	Read-across Please refer to confidential Annex
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<u>Product and packaging</u> (in HDPE): Packaging: Stable at 20 °C for 18.5 months <u>Appearance:</u> Initial: homogeneous, clear rust brown liquid, Pantone 4975 C 3 months: homogeneous, clear rust brown liquid, Pantone 4975 C 6 months: homogeneous, clear rust brown liquid, Pantone 4975 C 12 months: homogeneous, clear rust brown liquid, Pantone 4975 C 18.5 months: homogeneous, clear rust brown liquid, Pantone 4975 C <u>Packaging:</u> Initial: Sealed, no leaks 12 months: no change 18.5 months: no change <u>pH (CIPAC MT75.3):</u> Initial: 5.9 3 months: 5.8 6 months: 5.8 - 5.9 12 months: 5.7 - 5.8 18.5 months: 5.9 <u>Viscosity</u> (CIPAC MT192) Initial: 1.92 – 0.00 mPa.s at 181 – 5.6 min^{-1} 12 months: 1.68 – 0.00 mPa.s at 181 – 5.6 min^{-1} 18.5 months: 1.68 –	Manka, S. (2017) Report no. Mo5347

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			0.00 mPa.s at 181 – 5.6 min^{-1} <u>Relative Density:</u> Initial: D_4^{20} = 1.018 12 months: D_4^{20} = 1.018 18.5 months: D_4^{20} = 1.018 <u>Iodide:</u> Initial: 0.0416% 3 months: 0.0389% 6 months: 0.0340% 12 months: 0.0410% 18.5 months: 0.0082% <u>Iodine:</u> Initial: 0.151% 3 months: 0.149% 6 months: 0.144% 12 months: 0.139% 18.5 months: 0.137% <u>Total iodine:</u> Initial: 0.1926% 3 months: 0.1874% 6 months: 0.1776% 12 months: 0.1796% 18.5 months: 0.1451%	
		calgodip D 1200 <u>Iodine conc.</u> Available: 0.14 Total: 0.29	The product is similar in composition to a tested product of the BPF.	Read-across Please refer to confidential Annex
		calgodip D 3000 <u>Iodine conc.</u> Available: 0.34 Total: 0.72	<u>Product and packaging (in HDPE):</u> Stable at 20 °C for 24 months <u>Appearance:</u> Initial: homogeneous, turbid liquid, Pantone 490 C 3 months: homogeneous, turbid liquid, Pantone 490 C 6 months: homogeneous, turbid liquid, Pantone 490 C 12 months: homogeneous, turbid	Manka, S. (2017) Report No. Mo5345

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			liquid, Pantone 490 C 24 months: homogeneous, turbid liquid, darker than Pantone 490 C <u>Packaging:</u> Initial: Sealed, no leaks 12 months: no change 24 months: no change <u>pH (CIPAC MT75.3):</u> Initial: 5.5 - 5.6 3 months: 5.6 6 months: 5.5 12 months: 5.5 24 months: 5.5 – 5.6 <u>Viscosity (CIPAC MT192):</u> Initial: 3.36– <2 mPa.s at 181 – 5.6 min^{-1} 12 months: 2.88 – <2 mPa.s at 181 – 5.6 min^{-1} 24 months: 3.00. – <2 mPa.s at 181 – 5.6 min^{-1} <u>Relative Density:</u> Initial: D_4^{20} = 1.029 12 months: D_4^{20} = 1.029 24 months: D_4^{20} = 1.029 <u>Iodide:</u> Initial: 0.5216% 3 months: 0.5214% 6 months: 0.5171% 12 months: 0.5183% 24 months: 0.5194% <u>Iodine:</u> Initial: 0.339% 3 months: 0.339% 6 months: 0.338% 12 months: 0.337% 24 months: 0.335% <u>Total iodine:</u> Initial: 0.8608% 3 months: 0.8608% 6 months: 0.8550% 12 months: 0.8549% 24 months: 0.8548%	
		calgodip D 3000 Film <u>Iodine conc.</u> Available: 0.34	<u>Product and packaging (in HDPE):</u> Stable at 20 °C for 24 months <u>Appearance:</u>	Manka, S. (2017) Report No. Mo5348

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Total: 0.72	Initial: homogeneous, turbid liquid, Pantone 490 C 3 months: homogeneous, turbid liquid, Pantone 490 C 6 months: homogeneous, turbid liquid, Pantone 490 C 12 months: homogeneous, turbid liquid, Pantone 490 C 24 months: homogeneous, turbid liquid, darker than Pantone 490 C <u>Packaging:</u> Initial: Sealed, no leaks 12 months: no change 24 months: no change <u>pH (CIPAC MT75.3):</u> Initial: 5.6 3 months: 5.6 6 months: 5.6 12 months: 5.6 24 months: 5.6 – 5.8 <u>Viscosity (CIPAC MT192):</u> Initial: 26.64 – >140 mPa.s at 181 – 5.6 min^{-1} 12 months: 22.92 – >140 mPa.s at 181 – 5.6 min^{-1} 24 months: 28.80 – >140 mPa.s at 181 – 5.6 min^{-1} <u>Relative Density:</u> Initial: D_4^{20} = 1.032 12 months: D_4^{20} = 1.034 24 months: D_4^{20} = 1.034 <u>Iodide:</u> Initial: 0.5215% 3 months: 0.5209% 6 months: 0.5395% 12 months: 0.5266% 24 months: 0.5403% <u>Iodine:</u> Initial: 0.328% 3 months: 0.328% 6 months: 0.321% 12 months: 0.317% 24 months: 0.318%	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			Total iodine: Initial: 0.8496% 3 months: 0.8486% 6 months: 0.8600% 12 months: 0.8434% 24 months: 0.8584%	
		calgodip D 5000 Iodine conc. Available: 0.54 Total: 0.92	The product is similar in composition to a tested product of the BPF.	Read-across Please refer to confidential Annex

eCA remark

Shelf-life data suggests that for the duration of the tests (18.5 months) performed using the products in meta SPC 1 to 6, degradation of iodine exceeds 10%, with the exception for Dip es Io-foam (9.3% degradation). Efficacy data with aged samples were provided (see efficacy section), showing that the products are all still sufficiently efficacious after 18 months. A shelf-life of 18 months is therefore considered acceptable to the eCA.

For the calgodip products (Meta-SPC 7, 8 and 9), the shelf-life studies show that a shelf-life of 2 years is supported.

The analytical method used for determination of the iodine content is the same as the pharmacopoeia published titration method (see analytical method section, 1.2.4) and is considered sufficiently valid for its purpose.

pH

The pH of the products generally reduces during storage for the products within meta SPC1-6. The eCA considers this is related to the chemical instability of these products during storage. As for chlorine and bromine, iodine undergoes a number of reactions in water, which include a direct reaction in which acid is formed: I2 + H2O -> HOI + HI. If the hypoiodous acid (HOI) reacts by oxidising another component in the product, the reaction cannot reverse, leaving hydrons (H+) and iodide. This is expected to be the main reason for the reduced pH after storage.

After storage, none of the products drop below the classification and labelling threshold of pH 2. Considering the pH was <4 in some situations, the acidity would normally be required and the question arises whether the prerequisite the pH should remain within the range 4 – 6 is still met (general BPF specification). In this specific case it was accepted this data was not available as it was not necessary for either the risk assessment or classification and labelling purposes. The pH limitation for this product family was primarily intended to ensure stability and to prevent issues with regard to classification and labelling. Both these issues are addressed by efficacy data.

Degradation products

As the degradation of iodine exceeds 10% for most PVP-iodine based products, generally, this requires an evaluation of breakdown products. Iodine is a non-specific oxidiser, and its main degradation product is iodide, which is taken into account in the risk assessment (total elemental iodine within the products is used as input parameter). It is not feasible to determine which compounds were oxidised during the process. Therefore, the eCA accepts that there is no specific analytical data nor a risk assessment with regard to degradation products after storage.

Storage stability test – **low temperature**		All products Iodine conc.	The low temperature stability test is not required due to the label	Data waiving according to "Guidance on the

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
stability test for liquids		Available: 0.14-0.54 Total: 0.19-0.92	claim: "Protect from frost".	Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		All products <u>Iodine conc.</u> Available: 0.14-0.54 Total: 0.19-0.92	Opaque packaging, therefore no impact on content of active substance due to exposure to light expected.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		All products <u>Iodine conc.</u> Available: 0.14-0.54 Total: 0.19-0.92	*Temperature:* The effect of temperature on the content of the active substance is reported in the accelerated storage reports (storage at 30 or 40 °C). The results show that at elevated temperatures the iodine assay content decreases. Based on these results, it is concluded that temperatures above 30°C should be avoided. See conclusion after this table for more information. *Humidity:* Since all products of the biocidal product family are water-based formulations, humidity is not expected to influence their technical characteristics or the content of active substance during storage. The packaging is watertight, therefore preventing exchange of humidity between the products and the surroundings.	Please see reference of the storage stability test(s) for each individual product.
Effects on content of the		All products	Reactivity towards container material	Please see reference of the accelerated

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	covered in accelerated storage stability tests. No signs of reactivity towards container material were observed. Reactivity towards container material will be further evaluated in long term storage stability tests.	storage stability test(s) for each individual product.
Wettability		All products Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products and not solids.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A",vers. 1.1, Nov. 2014
Suspensibility, spontaneity and dispersion stability		All products Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products and not suspension concentrates.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Wet sieve analysis and dry sieve test		All products Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Emulsifiability, re-emulsifiability and emulsion stability		All products Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products. They are neither emulsions nor form emulsions.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Disintegration time		All products Iodine conc. Available: 0.14-0.54 Total: 0.19-0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products and not tablets.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Particle size distribution, content of		All products Iodine conc.	Not applicable. All products of this BPF are water-based ready-to-	Data waiving according to "Guidance on the

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
dust/fines, attrition, friability		Available: 0.14 - 0.54 Total: 0.19 - 0.92	use (RTU) products and not powder or granules.	Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Persistent foaming		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products which do not need to be dispersed in water before use. Furthermore, the test is not required when the product is intended for foam applications. Foam applications are relevant for Dip es Io-foam, calgodip D 1200 and calgodip D 3000 Film.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Flowability/Pourability/Dustability		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) products and not suspensions nor emulsions.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Burning rate — smoke generators		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) liquid products and not smoke generators.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Burning completeness — smoke generators		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) liquid products and not smoke generators.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Composition of smoke — smoke generators		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based ready-to-use (RTU) liquid products and not smoke generators.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Spraying	Similar to		**eCA remark**	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
pattern — aerosols	FEA 644		Although the product(s) in this family are not aerosols and not sold in packs with a spray attachment, the applicant has provided data on spray characteristics using representative sprayers. Such information is not strictly required and is considered as supplementary data.	
		Dip es silver <u>Iodine conc.</u> Available: 0.30 Total: 0.40	Spray diameter (at 20 ± 2°C) = 29.0 cm, fine spray jet with speckled spray pattern Dip es silver is not sold in spraying equipment. In particular, it is not sold as aerosol can. The test has been performed with a trigger sprayer independently sold by the product supplier.	Manka, S. (2015) Report no. Mo5242
		Dip es SF <u>Iodine conc.</u> Available: 0.14 Total: 0.19	Spray diameter (at 20 ± 2°C) = 31.0 cm, fine spray jet with speckled spray pattern Dip es SF is not sold in spraying equipment. In particular, it is not sold as aerosol can. The test has been performed with a trigger sprayer independently sold by the product supplier.	Manka, S. (2015) Report no. Mo5242
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	Spray diameter (at 20 ± 2°C) = 36.0 cm, fine spray jet with speckled spray pattern Dip es Io-foam is not sold in spraying equipment. In particular, it is not sold as aerosol can. The test has been performed with a trigger	Affolter, O. (2015) Report no. 15031703N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
			sprayer independently sold by the product supplier.	
	FEA 644; Filled Aerosol Packs – Evaluation of Aerosol Spray Patterns – 03/2009	calgodip D 1200 <u>Iodine conc.</u> Available: 0.14 Total: 0.29	Spray rate = 1.21 g/stroke Spray pattern: not geometric circular (heart-shaped), 18.5 x 19 cm Calgodip D 1200 is not sold in or together with spraying equipment. In particular, it is not sold as aerosol can. The test has been performed with a commercially available trigger sprayer.	Affolter, O. (2015) Report no. 15031613N978
		calgodip D 3000 <u>Iodine conc.</u> Available: 0.34 Total: 0.72	Spray rate = 1.24 g/stroke Spray pattern: circular, 20 x 20 cm Calgodip D 3000 is not sold in or together with spraying equipment. In particular, it is not sold as aerosol can. The test has been performed with a commercially available trigger sprayer.	Affolter, O. (2015) Report no. 15031611N978
		Dip es barriere RS <u>Iodine conc.</u> Available: 0.50 Total: 0.67	Dip es barriere RS, Dip es barrier S, Dip es barriere, Dip es Io-film, calgodip D 3000 Film and calgodip D 5000 are not intended to be used for spray applications.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
		Dip es barriere S <u>Iodine conc.</u> Available: 0.30 Total: 0.40		
		Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19		

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Dip es lo-film <u>Iodine conc.</u> Available: 0.0.30 Total: 0.40		
		calgodip D 3000 Film <u>Iodine conc.</u> Available: 0.34 Total: 0.72		
		calgodip D 5000 <u>Iodine conc.</u> Available: 0.54 Total: 0.92		
Physical compatibility		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. None of the products of this BPF are recommended to be used in combination with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Chemical compatibility		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. None of the products of this BPF are recommended to be used in combination with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Degree of dissolution and dilution stability		All products <u>Iodine conc.</u> Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based liquid ready-to-use (RTU) products which do not need to be dispersed in water before use.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014
Surface tension	EU Method A.5	Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19	52.3 mN/m (T = 20 °C) Surface active	Manka, S. (2015) Report no. Mo5242
		Dip es silver	63.7 mN/m	Manka, S. (2015)

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		<u>Iodine conc.</u> Available: 0.30 Total: 0.40	(T = 20 °C) Not surface active	Report no. Mo5242
		Dip es SF <u>Iodine conc.</u> Available: 0.14 Total: 0.19	62.0 mN/m (T = 20 °C) Not surface active	Manka, S. (2015) Report no. Mo5242
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	64.2 mN/m (T = 20 °C) Not surface active	Manka, S. (2015) Report no. Mo5242
	EU Method A.5 OECD Guideline 115	Dip es barriere RS <u>Iodine conc.</u> Available: 0.50 Total: 0.67	64.62 - 65.08 mN/m (T = 20 °C) Not surface active	Affolter, O. (2015) Report no. 15031706N978
		Dip es barriere S <u>Iodine conc.</u> Available: 0.30 Total: 0.40	66.65 - 67.30 mN/m (T = 20 °C) Not surface active	Affolter, O. (2015) Report no. 15031708N978
		Dip es lo-film <u>Iodine conc.</u> Available: 0.0.30 Total: 0.40	67.09 - 67.55 mN/m (T = 20 °C) Not surface active	Affolter, O. (2015) Report no. 15031703N978
		calgodip D 1200 <u>Iodine conc.</u> Available: 0.14 Total: 0.29	49.47 - 50.62 mN/m (T = 20 °C) Surface active	Affolter, O. (2015) Report no. 15031613N978
		calgodip D 3000 <u>Iodine conc.</u> Available: 0.34 Total: 0.72	39.76 - 40.86 mN/m (T = 20 °C) Surface active	Affolter, O. (2015) Report no. 15031611N978
		calgodip D 3000 Film	For technical reasons, a surface tension test	

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		<u>Iodine conc.</u> Available: 0.34 Total: 0.72	according to EU Method A.5 or OECD Guideline 115 has not been performed for calgodip D 3000 Film. As this product is a viscous liquid, the high viscosity would interfere with the ring test method.	
		calgodip D 5000 <u>Iodine conc.</u> Available: 0.54 Total: 0.92	For technical reasons, a surface tension test according to EU Method A.5 or OECD Guideline 115 has not been performed for calgodip D 5000. As this product is a viscous liquid, the high viscosity would interfere with the ring test method.	
eCA remark The surface tension of the products within the family ranges from around 40 to 70 mN/m. The products in meta SPCs 7 and 8 are expected to have a lower surface tension based on their composition. As the surface tension is not a driving force with regard to risk or efficacy, the data is considered sufficiently representative for the family.				
Viscosity	CIPAC MT 192	Dip es barriere RS <u>Iodine conc.</u> Available: 0.50 Total: 0.67	709 mPa s (100 min^{-1}) – 5027 mPa s (10 min^{-1}) (T = 20.0 °C); 641 mPa s (100 min^{-1}) – 4607 mPa s (10 min^{-1}) (T = 40.0 °C)	Affolter, O. (2015) Report no. 15031706N978
		Dip es barriere S <u>Iodine conc.</u> Available: 0.30 Total: 0.40	536 mPa s (100 min^{-1}) – 3727 mPa s (10 min^{-1}) (T = 20.0 °C); 465 mPa s (100 min^{-1}) – 3410 mPa s (10 min^{-1}) (T = 40.0 °C)	Affolter, O. (2015) Report no. 15031708N978
		Dip es barriere <u>Iodine conc.</u> Available: 0.14 Total: 0.19	20.58 mPa s (181 min^{-1}) – 284.16 mPa s (5.6 min^{-1}) (T = 20 °C)	Manka, S. (2015) Report no. Mo5242
		Dip es lo-film <u>Iodine conc.</u> Available: 0.0.30 Total: 0.40	525 mPa s (100 min^{-1}) – 3817 mPa s (10 min^{-1}) (T = 20.0 °C); 525 mPa s (100 min^{-1}) – 3738 mPa s (10 min^{-1}) (T = 40.0 °C)	Affolter, O. (2015) Report no. 15031703N978

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
		Dip es silver <u>Iodine conc.</u> Available: 0.30 Total: 0.40	8.16 mPa s (181 min^{-1}) – 53.76 mPa s (5.6 min^{-1}) (T = 20 °C)	Manka, S. (2015) Report no. Mo5242
		Dip es SF <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<2 mPa s (181 min^{-1}) – 3.84 mPa s (5.6 min^{-1}) (T = 20 °C)	Manka, S. (2015) Report no. Mo5242
		Dip es Io-foam <u>Iodine conc.</u> Available: 0.14 Total: 0.19	<2 mPa s (181 min^{-1}) – 3.84 mPa s (5.6 min^{-1}) (T = 20 °C)	Manka, S. (2015) Report no. Mo5242
		calgodip D 1200 <u>Iodine conc.</u> Available: 0.14 Total: 0.29	<5 mPa s (T = 20.0 °C)	Affolter, O. (2015) Report no. 15031613N978
		calgodip D 3000 <u>Iodine conc.</u> Available: 0.34 Total: 0.72	<5 mPa s (T = 20.0 °C)	Affolter, O. (2015) Report no. 15031611N978
		calgodip D 3000 Film <u>Iodine conc.</u> Available: 0.34 Total: 0.72	1230 mPa s (50 min^{-1}) – 19520 mPa s (2 min^{-1}) (T = 20.0 °C)	Affolter, O. (2015) Report no. 15031610N978
		calgodip D 5000 <u>Iodine conc.</u> Available: 0.54 Total: 0.92	107 mPa s (50 min^{-1}) – 341 mPa s (2 min^{-1}) (T = 20.0 °C)	Affolter, O. (2015) Report no. 15031612N978
eCA remark Products in Meta SPCs 1 to 4, 7 and 9 contain film formers and/or thickeners, which is consistent with the data. Considering the ranges within the family compositions are quite narrow, the data provided is considered sufficiently representative.				

Conclusion on the physical, chemical and technical properties of the product

Physical and chemical properties
The product family contains products with different characteristics. All products were tested for their physical and chemical properties with regard to appearance, density, pH, surface tension and viscosity. The studies are all acceptable.

All products within the family should have a pH in the range 4 – 6. Outside this pH range, the stability of the products cannot be guaranteed.

Relating to this fact, storage at elevated temperatures is not recommended. A restriction for storage >30°C is necessary. Products within meta SPCs 1 to 6 showed a significant decrease in pH during the accelerated storage stability trials.

Family structure justification
A justification for the family structure is provided in the confidential Annex detailing as to why the studies provided should be considered representative for the individual meta-SPCs.

Accelerated storage stability
Total iodine values (sum of available iodine and iodide) after 4 weeks stayed relatively constant ranging between 98.0% (Dip es silver) and 100.1% (Dip es Io-foam) of the T0 values.

The total iodine results demonstrate that although iodine degradation of generally > 5% after the storage period occurred, total iodine values stayed constant. In conclusion, this means, that the major degradation product of iodine is indeed iodide. In the human health and environmental exposure and risk assessments the total iodine content of the products has been taken into account, thus covering not only exposure and subsequent risk from the active substance (available) iodine but also for its major degradation product iodide.
Based on the results of the accelerated storage stability tests, it is further concluded that temperatures above 30°C should be avoided in storage, particularly for PVP-iodine containing products.

Long-term storage stability at ambient temperature
Dip es products
Long-term storage stability studies have been performed for Dip es barriere, Dip es lo-film, Dip es silver and Dip es Io-foam in HDPE packaging at ambient temperature. After 18.5 months of storage, iodine values ranged from 90.7% (Dip es Io-foam) to 71.9% (Dip es barriere) of the T0 values. Total iodine values (sum of available iodine and iodide) stayed relatively constant for Dip es barriere, Dip es lo-film and Dip es silver ranging between 90.4% (Dip es barriere) to 98.2% (Dip es Io-film) of the T0 values.

Since with the exception of Dip es Io-foam, the degradation of iodine was > 10% for all tested products (but < 10% for total iodine), efficacy data after storage has been generated for Dip es barriere, Dip es lo-film, Dip es silver and Dip es Io-foam. In both an EN1656 and EN1657 test performed with the stored products, adequate efficacy could be demonstrated (see chapter 2.2.5).

The study data (ambient storage stability and efficacy) for Dip es barriere, Dip es lo-film and Dip es silver supports a shelf-life claim of 18 months.
Although for Dip es Io-foam available iodine degradation was < 10% after 18.5 months of storage at ambient temperature and appropriate efficacy could be demonstrated after this storage period, total iodine degradation was > 10% after 18.5 months (but < 10%

after 12 months: 93.3% of T0). Hence, for Dip es Io-foam, a shelf-life of 12 months was claimed by the applicant. The eCA considers it to be impossible that the element iodine (in the form of iodide) broke down and expects the observed drop in iodide content to be caused by an analytical error. Based on this consideration, a shelf-life claim of 18 months is supported for the product Dip es Io-foam as well.

Calgodip products
The final reports of the long-term storage stability studies in HDPE show that the products within meta SPCs 7, 8 and 9 are stable for 2 years at ambient conditions. Degradation of the iodine content remained <10%. Therefore, no efficacy data was generated.

1.2.3 Physical hazards and respective characteristics

Introductory remark
Physical hazards and respective characteristics are generally waived for all products of the BPF according to the "Guidance on the Biocidal Products Regulation, Volume I, Part A", vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components which are classified as explosive. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to be explosive.	Data waiving
Flammable gases		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not flammable gases.	Data waiving
Flammable aerosols		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components which are classified as flammable aerosol. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to from a flammable aerosol if sprayed.	Data waiving
Oxidising gases		All products Iodine conc. Available: 0.14 - 0.54 Total:	Not applicable. All products of this BPF are water-based, liquid formulations and not oxidising gases.	Data waiving

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		0.19 - 0.92		
Gases under pressure		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid products and not gases under pressure.	Data waiving
Flammable liquids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	With the exception of only residual amounts of acetic acid, the products do not contain any flammable substances. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to be flammable.	Data waiving
Flammable solids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not flammable solids.	Data waiving
Self-reactive substances and mixtures		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components or mixtures which are classified as self-reactive. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to be self-reactive.	Data waiving
Pyrophoric liquids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components which are classified as pyrophoric liquid. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to have pyrophoric properties.	Data waiving
Pyrophoric solids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not pyrophoric solids.	Data waiving
Self-heating		All products	None of the products contain	Data waiving

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
substances and mixtures		Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	components which are classified as self-heating. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to be self-heating.	
Substances and mixtures which in contact with water emit flammable gases		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components or mixtures which are classified as water-reactive. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to release flammable gases which my ignite spontaneously.	Data waiving
Oxidising liquids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components which are classified as oxidising liquid. Due to the intrinsic properties of the individual components, the high water content and known experience, the oxidising properties of all formulations of the BPF are predicted negative.	Data waiving
Oxidising solids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not oxidising solids.	Data waiving
Organic peroxides		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	None of the products contain components which are classified as organic peroxides. Due to the intrinsic properties of the individual components, the high water content and known experience, none of the formulations of the BPF is expected to cause a fire or explosion.	Data waiving
Corrosive to metals	UN Test C.1 as described in Section 37.4 of the UN-MTC	Calgodip D 5000 Iodine conc. Available: 0.54% Total: 0.92%	Not corrosive to metals	Eschbach, B. (2018) Report no. BE01-01-2018

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Dip es silver Iodine conc. Available: 0.30% Total: 0.40%	Not corrosive to metals	Eschbach, B. (2018) Report no. BE01-02-2018
eCA remark Corrosiveness to metals was investigated for the worst-case products Calgodip D5000 (highest iodine content) and Dip es silver (lowest pH). For Calgodip, steel (St 37-2) was tested during 14 days. The intrusion depth was <100 µm for all tests (immersed, 50% immersed and in the gas phase). Weight loss was no more than 3.64% (50% immersion). Aluminium (7075-T6) was tested for 7 days. No pitting was observed at all and mass loss was no more than 0.63% (gas phase). The conclusion is therefore that Calgodip D5000 does not meet the classification criteria for corrosiveness to metals. For Dip es silver the same tests were performed. The same grade of steel was tested for 14 days, with a maximum weight loss of 6.89% (gas phase) and <100µm intrusion depth. For aluminium no pitting was observed and the weight loss was no more than 0.80% (gas phase). The conclusion is therefore that Dis es silver does not meet the classification criteria for corrosiveness to metals.				
Auto-ignition temperatures of products (liquids and gases)		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	The products do not contain flammable co-formulants. Due to the intrinsic properties of the individual components, the high water content and known experience, auto-ignition properties of all formulations of the BPF are predicted negative.	Data waiving
Relative self-ignition temperature for solids		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not solids.	Data waiving
Dust explosion hazard		All products Iodine conc. Available: 0.14 - 0.54 Total: 0.19 - 0.92	Not applicable. All products of this BPF are water-based, liquid formulations and not solids which may form dust.	Data waiving

Conclusion on the physical hazards and respective characteristics of the product
The products of the Teat disinfectants biocidal product family of CVAS are not classified with regard to their physical and chemical properties.

1.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
The titration of iodine with sodium thiosulphate is described in the European Pharmacopoeia (*Ph. Eur.*), and can, thus, be considered a validated, robust and reliable analytical method. Nevertheless, the titration method has been implemented for the products Dip es barriere, Dip es barriere S2 (a formulation similar in composition and active substance content to the BPF member Dip es barriere S; Dip es barriere S2 contains, however, 0.6% phosphoric acid (75%)), calgodip D 3000 and calgodip D 5000. Accuracy in the range of 70 – 130 % has been demonstrated for the lowest and the highest iodine content of 0.14 and 0.54%, respectively. Reproducibility was demonstrated to be in the range of 0.5 – 1.3%. Therefore, it can be expected that the titration method is valid (i.e. specific, linear, precise, accurate and reproducible) for all products pertaining to the BPF.									

eCA remarks
The pharmacopoeia method is expected to be suitable for the products within the family. None of the co-formulants are expected to interfere with the titration method.

The accuracy was determined with blank products, spiked with 70, 100 and 130% of the nominal content of iodine. Recoveries were 102 - 103% for calgodip D3000 and 104 – 111% for calgodip D5000. The 111% value appears to be an outlier, but this was not investigated by the reporting lab.
Linearity was determined using standard addition over a range of 70 – 130% of the nominal content (n = 4).
System precision was addressed by measuring two replicates of three samples.

Although the outcome of the recovery experiment showed one unexpected high value and the precision was not determined by analysis of 5 replicate samples, the eCA considers that the published pharmacopoeia method is generally acceptable for determination of iodine in products.

Iodide content
In some of the shelf-life studies a method for determination of iodide was used as well. This method was not reported in the analytical method section. The method used is a published method as well (Pharmacopoeia, Ph. Eur. 01/2005:1142). By adding sodium metabisulfite, all iodine is converted to iodide prior adding silver nitrate, nitric acid and ferric ammonium suphate, followed by tritration with ammonium thiocyanate.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Analytical methods for the determination of iodine are presented in the CAR, Dec. 2013, Doc III A4.2 and A4.3.									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant, however analytical methods for determination of iodine in soil are presented in the CAR, Dec. 2013, Doc III A4.2.									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Spraying use: May be relevant for worker exposure in spray applications. Analytical methods for determination of iodine in air are presented in CAR, Dec. 2013, Doc III A4. Other uses (e.g. dipping, foaming uses): Not relevant, however analytical methods for determination of iodine in air are presented in the CAR, Dec. 2013, Doc III A4.2.									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant, however analytical methods for determination of iodine in water are presented in the CAR, Dec. 2013, Doc III A4.2.									

Analytical methods for animal and human body fluids and tisues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant, as the active substance iodine is not classified as toxic or very toxic.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Analytical methods for determination of iodine residues in milk are presented in the CAR, Dec. 2013, Doc III A4.3.									

Conclusion on the methods for detection and identification of the product
The published pharmacopoeia method provided is acceptable to determine the content of the active substance iodine in the products of the Teat disinfectants biocidal product family of CVAS. Monitoring methods for the determination of residues in soil, air, water and food and feeding stuffs are provided in the CAR, Dec. 2013, Doc III A4.2 and 4.3. No additional data is deemed necessary in support of this application.

1.2.5 Efficacy against target organisms

1.2.5.1 Function and field of use

The product family comprises 9 *meta* SPCs, including 11 biocidal products, based on the active substance iodine and PVP-iodine for the use as non-medical teat disinfectants in veterinary hygiene (PT3). These are liquid ready-to-use products with an intended use concentrations in the range of 0.14-0.54% (1400-5400 ppm) available iodine. They can be applied by dipping, foaming or spraying, either manual or automated. The products in meta-SPCs 1 to 5 and meta-SPCs 7-9 are intended to be used after milking. The foaming products in meta-SPC 6 are intended to be used before and/or after milking. The use is restricted for professionals only.

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

The biocidal products reduce the number of vegetative cells of bacteria and viable yeast cells that occur on the skin of teats of milk producing animals such as dairy cows. The

products are applied in order to increase the hygienic status of the teat skin and the hygiene of raw milk, and thus to ensure animal and food safety.

1.2.5.3 Effects on target organisms, including unacceptable suffering

The biocidal products in this family have a bactericidal and yeasticidal activity. This has been demonstrated according the international guidelines EN 1656 and EN 1657.
In addition, CVAS Development GmbH, as member of the PT3 sub-group of the Iodine Registration Group (IRG), has been working on the development of a surface test (phase 2 step 2) with artificial skin. Tests according to this new (draft) protocol have been performed for this family.

1.2.5.4 Mode of action, including time delay

The mode of action of iodine is non-selective and is based on the following mechanisms:

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

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

1.2.5.5 Efficacy data

The bactericidal and yeasticidal efficacy of the teat disinfectants was tested in suspension tests according to the international standards EN 1656 and EN 1657 under test conditions defined for teat disinfection. EN 1657 was modified by choosing additional test conditions regarding test temperature, interfering substance and contact time as given in EN 1656 for teat disinfectants because no standard exists to test yeasticidal activity of teat disinfectants.
The laboratory studies were performed with strains of gram-positive and gram-negative bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*) and yeasts (*Candida albicans*), representative for teat disinfection.

For the phase 2 step 2 surface test with artificial skin (modified EN 16437) developed by the IRG PT3-sub-group, the BPC WG-V-2015 concluded that for post-milking disinfection a lg4 reduction is required with a contact time of max 5 min., while for pre-milking disinfection a contact time of 30 sec. and lg3 may be accepted, if justified. Soiling conditions should be reflected in the test in accordance with the efficacy PT1-5 guidance

document. The PT3 sub-group regards the following soiling as appropriate for phase 2 step 2 testing:

- Pre-milking: bovine albumin (3 g/L final concentration) as interfering substance, taking into account that normally teats are cleaned before milking so that low soiling conditions prevail,

- Post-milking: skimmed milk (10 g/l final concentration) as interfering substance taking into account that after milking, milk residues may be present on the teats.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Keys studies meta-SPC 1-6							
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es SF (0.14% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-4-2015, key*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es SF (0.14% available iodine)	*Candida albicans*	EN 1657:2005 /AC, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%*	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1657, D9-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1657, D9-5-2015, key*

					Reduction factor: ≥4 lg	post-milking teat disinfection.	
PT3, biocidal product, yeasticidal activity (bridging study)	teat disinfection, pre-milking (bridging study)	Dip es SF (0.14% available iodine)	*Candida albicans (worst-case test organism of phase 2, step 1 tests)*	EN 1657(2005/AC:2007), modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 0.3% BSA Contact time: 30 sec, 60 sec Test concentration: 0.5%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 (0.3% BSA) is: 30 seconds, 60 seconds at 100%*.	*Kremlova, E. (2016) B6.7.* DIP ES SF, *EN1657, bridging study, D104/2016*
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es SF (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Drop Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 1%, 50%, 100%* Reduction factor: ≥4 lg (acc. to BPC WG Efficacy)	The tested product Dip es SF, decreased the number of *Staphylo-coccus aureus* under the test conditions defined for **post-milking** teat disinfectants by > lg **4.53** at a concentration of 50% and 100%* after 5 min contact time The results comply with the requirements for post-milking teat disinfection.	*Gerhardts, A. (2016): B6.7. Dip es SF, modified EN16437, post-milking, 16.8.1.019 4, key*
PT3, biocidal product, bactericidal activity	teat disinfection, pre- and post-milking	Dip es Io-foam (0.14% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time:	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 is: 30 seconds,	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES IO-FOAM, EN1656, D7-1-2015, key* *Slitrova, J.; Kremlova, E. (2015):*

					30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%* Reduction factor: ≥5 lg	60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*B6.7 DIP ES IO FOAM, EN1656, D7-4-2015, key*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es Io-foam (0.14% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES IO-FOAM, EN1657, D7-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES IO-FOAM, EN1657, D7-5-2015, key*
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Dip es Io-foam (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Dip Interfering substance: 0.3% BSA Test temperature: 30°C Contact time: 60s Test concentration: 1%, 50%, 100%* Reduction factor: ≥3 lg (acc. to BPC	The tested product Dip es Io-foam, decreased the number of *Staphylo-coccus aureus* under the test conditions defined for **pre-milking** teat disinfectants by lg **4.47** at a concen-tration of 100%* after 60 s contact time.	*Teulier, M. (2017): B6.7, Dip es Io-foam, modified EN16437, pre-milking, 4479-1, key*

					WG Efficacy)		
Key studies meta-SPC 7, 8 and 9							
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	calgodip D 1200 (0.14% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1656, D12-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1656, D12-4-2015, key*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	calgodip D 1200 (0.14% available iodine)	*Candida albicans*	EN 1657:2005 /AC, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1657, D12-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1657, D12-5-2015, key*
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	calgodip D 1200 (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Drop	The tested product calgodip D 1200, decreased the number of *Staphylo-coccus aureus* under the test conditions defined for post-milking teat disinfectants	*Gerhardts, A. (2016): B6.7.* calgodip D 1200*, modified EN16437, post-milking, 16.8.1.0195, key*

					Interfering substance: 1% **skimmed milk post milking** Test temperature: 30°C Contact time: 5 min Test concentration: 1%, 50%, 100%* Reduction factor: ≥4 lg (acc. to BPC WG Efficacy)	by > lg **4.61** at a concentration of 100%* after 5 min contact time The results comply with the requirements for post-milking teat disinfection.	
Additional studies meta-SPC 1-6							
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es barriere RS (0.5% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES BARIERRE RS, EN1656, D8-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-4-2015, key*[(1)]
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es barriere RS (0.5% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES BARIERRE RS, EN1657, D8-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1657, D9-5-2015, key*[(1)]
PT3, biocidal product,	teat disinfection, post-	Dip es barriere S (0.3%	*Escherichia coli, Staphylococc*	EN 1656	Quantitative suspension test	The bactericidal concentration	*Slitrova, J.; Kremlova, E. (2015):*

bactericidal activity	milking	available iodine)	*us aureus, Streptococcus uberis*		Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 100%* Reduction factor: ≥5 lg	determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*B6.7 DIP ES BARIERRES, EN1656, D125-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-4-2015, key*[(1)]
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es barriere S (0.3% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES BARIERRES, EN1657, D125-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1657, D9-5-2015, key*[(1)]
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es barriere (0.14% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES BARIERRE, EN1656, D4-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-4-2015, key*[(1)]
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es barriere (0.14% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions	Quantitative suspension test Interfering substance: 1% skimmed milk	The yeasticidal concentration determined under test conditions for teat	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES BARIERRE, EN1656,*

				as given in EN 1656 for teat disinfectants	Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*D4-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-5-2015, key[(1))]*
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es Io-film (0.3% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES IO-FILM, EN1656, D6-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1656, D9-4-2015, key[(1)]*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es Io-film (0.3% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES IO-FILM, EN1657, D6-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SF, EN1657, D9-5-2015, key[(1)]*
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es silver (0.3% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 is:	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SILVER, EN1656, D5-1-2015, key* *Slitrova, J.; Kremlova, E. (2015):*

					Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%* Reduction factor: ≥5 lg	30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*B6.7 DIP ES SILVER, EN1656, D5-4-2015, key*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es silver (0.3% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 50%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SILVER, EN1657, D5-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 DIP ES SILVER, EN1657, D5-5-2015, key*
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Dip es SF (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Drop Interfering substance: 0.3% BSA Test temperature: 30°C Contact time: 30s, 60s Test concentration: 1%, 50%, 100%* Reduction factor: ≥3 lg	The tested product Dip es SF, decreased the number of *Staphylococcus aureus* under the test conditions defined for **pre-milking** teat disinfectants by lg **2.03** at a concentration of 50% and 100%* after 30 s contact time; by lg **1.66** at a concentration of 50% and 100%* after 60 s contact time	*Gerhardts, A. (2016): B6.7. Dip es SF, modified EN16437, pre-milking, 16.8.1.0194, key*

					(acc. to BPC WG Efficacy)		
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	Dip es SF (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Dip Interfering substance: 0.3% BSA Test temperature: 30°C Contact time: 60s Test concentration: 1%, 50%, 100%* Reduction factor: ≥3 lg (acc. to BPC WG Efficacy)	The tested product Dip es SF, decreased the number of *Staphylococcus aureus* under the test conditions defined for **pre-milking** teat disinfectants by lg < **3.32** at a concentration of 100%* after 60 s contact time. (Not enough dilutions to be sure: dilution 10^{-1}: >330 cfu dilution 10^{-2}: 23 / 26 cfu. Based on mean 25 cfu log red = 3.3.2)	*Teulier, M. (2017): B6.7, Dip es SF, modified EN16437, pre-milking, 4478-1, key*
Additional studies meta-SPC 7, 8 and 9							
PT3, biocidal product, yeasticidal activity (bridging study)	teat disinfection, pre - milking (bridging study)	calgodip D 1200 (0.14% available iodine)	*Candida albicans (worst-case test organism of phase 2, step 1 tests)*	EN 1657(2005/AC:2007), modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 0.3% BSA Contact time: 30 sec, 60 sec Test concentration: 0.5%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 (0.3% BSA) is: 30 seconds, 60 seconds at 100%*.	*Kremlova E. (2016) B6.7. calgodip D 1200, EN1657, bridging study, D105/2016*
PT3, biocidal product, bactericidal activity	teat disinfection, pre-milking	calgodip D 1200 (0.14% available iodine)	*Staphylococcus aureus (worst-case test organism of phase 2, step 1 tests)*	modified EN 16437; test protocol developed by the IRG PT3-sub group phase 2 step 2 test	Modified test for porous surfaces (EN 16437) using artificial skin, developed by IRG PT3 sub-group Skin model: Vitroskin Method: Drop/Drop Interfering	The tested product calgodip D 1200, decreased the number of *Staphylococcus aureus* under the test conditions defined for pre-milking teat disinfectants by lg **1.76** at	*Gerhardts, A. (2016): B6.7.* calgodip D 1200*, modified EN16437, pre-milking, 16.8.1.0195, key*

					substance: 0.3% **BSA pre-milking** Test temperature: 30°C Contact time: 30s, 60s Test concentration: 1%, 50%, 100%* Reduction factor: ≥3 lg (acc. to BPC WG Efficacy)	a concen-tration of 100%* after 30 s contact time; by lg **2.43** at a concentration of 50% after 30 s contact time by lg **1.65** at a concen-tration of 100%* after 60 s contact time; by lg **2.41** at a concentration of 50% after 60 s contact time	
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	calgodip D 3000 (0.34% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for pre- and post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000, EN1656, D10-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000, EN1656, D10-4-2015, key*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	calgodip D 3000 (0.34% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30 sec, 60 sec, 5 min Test concentration: 0.5%, 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 is: 30 seconds, 60 seconds and 5 minutes at 100%*. The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000, EN1657, D10-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000, EN1657, D10-5-2015, key*

PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	calgodip D 3000 Film (0.34% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000 FILM, EN1656, D11-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1656, D12-4-2015, key*[(2)]
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	calgodip D 3000 Film (0.34% available iodine)	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 3000 FILM, EN1657, D11-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1657, D12-5-2015, key*[(2)]
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	calgodip D 5000 (0.54% available iodine)	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 5000, EN1656, D13-1-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1656, D12-4-2015, key*[(2)]
PT3, biocidal product, yeasticidal	teat disinfection, post-milking	calgodip D 5000 (0.54% available	*Candida albicans*	EN 1657, modified by choosing	Quantitative suspension test	The yeasticidal concentration determined	*Slitrova, J.; Kremlova, E. (2015): B6.7*

activity		iodine)		additional test conditions as given in EN 1656 for teat disinfectants	Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 100%* Reduction factor: ≥4 lg	under test conditions for teat disinfection according to EN 1657 after 5 minutes contact time is: 100%* The results comply with the requirements for post-milking teat disinfection.	*CALGODIP D 5000, EN1657, D13-2-2015, key* *Slitrova, J.; Kremlova, E. (2015): B6.7 CALGODIP D 1200, EN1657, D12-5-2015, key*[(2)]
Studies with aged products							
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es barriere (0.14% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.105% - please refer to the determination of the active substance content in the chapter long term storage at ambient temperature provided in the study Mo5349	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656 (2010-03)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 80%, 50%, 0.5% Reduction factor: ≥5 lg	The bactericidal concentration is determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES BARRIERE (after 18.5 months storage), EN1656, 306.17-2*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es barriere (0.14% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.105% - please refer to the determina	*Candida albicans*	EN 1657 (2016)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30, 60 s Test concentration: 80%, 50%, 0.5%	The yeasticidal concentration is determined under test conditions for teat disinfection according to EN 1657 after 30 and 60 seconds contact time and after **18.5 months storage**. The minimum effective	*Bartuli, J. (2017): B6.7 DIP ES BARRIERE (after 18.5 months storage), EN1657, 306.17-2*

		tion of the active substance content in the chapter long term storage at ambient temperature provided in the study Mo5349			Reduction factor: ≥4 lg	concentration is: 50%	
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es Io-film (0.3% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.262% - please refer to the determination of the active substance content in the chapter long term storage at ambient temperature provided in the study Mo5350	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656 (2010-03)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 80%, 50%, 0.5% Reduction factor: ≥5 lg	The bactericidal concentration is determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES IO-FILM (after 18.5 months storage), EN1656, 306.17-3*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es Io-film (0.3% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.262% - please refer to the determination of the active substance	*Candida albicans*	EN 1657 (2016)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30, 60 s Test concentration: 80%, 50%, 0.5% Reduction	The yeasticidal concentration is determined under test conditions for teat disinfection according to EN 1657 after 30 and 60 seconds contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES IO-FILM (after 18.5 months storage), EN1656, 306.17-3*

		content in the chapter long term storage at ambient temperature provided in the study Mo5350			factor: ≥4 lg		
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es silver (0.3% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.240% - please refer to the determination of the active substance content in the chapter long term storage at ambient temperature provided in the study Mo5346	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656 (2010-03)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 80%, 50%, 0.5% Reduction factor: ≥5 lg	The bactericidal concentration is determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES SILVER (after 18.5 months storage), EN1656, 306.17-1*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es silver (0.3% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.240% - please refer to the determination of the active substance content in	*Candida albicans*	EN 1657 (2016)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30, 60 s Test concentration: 80%, 50%, 0.5% Reduction factor: ≥4 lg	The yeasticidal concentration is determined under test conditions for teat disinfection according to EN 1657 after 30 and 60 seconds contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES SILVER, EN1657 (after 18.5 months storage), 306.17-1*

		the chapter long term storage at ambient temperature provided in the study Mo5346					
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	Dip es Io-foam (0.14% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.137% - please refer to the determination of the active substance content in the chapter long term storage at ambient temperature provided in the study Mo5347	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656 (2010-03)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentration: 80%, 50%, 0.5% Reduction factor: ≥5 lg	The bactericidal concentration is determined under obligatory test conditions for teat disinfection according to EN 1656 after 5 minutes contact time and **after 18.5 months** storage. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES IO-FOAM (after 18.5 months storage), EN1656, 307.17-4*
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	Dip es Io-foam (0.14% available iodine; nominal value) available iodine content after 18.5 months of storage: 0.137% - please refer to the determination of the active substance content in the	*Candida albicans*	EN 1657 (2016)	Quantitative suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 30, 60 s Test concentration: 80%, 50%, 0.5% Reduction factor: ≥4 lg	The yeasticidal concentration is determined under test conditions for teat disinfection according to EN 1657 after 30 and 60 seconds contact time and after **18.5 months storage**. The minimum effective concentration is: 50%	*Bartuli, J. (2017): B6.7 DIP ES IO-FOAM (after 18.5 months storage), EN1657, 307.17-4*

		chapter long term storage at ambient temperature provided in the study Mo5347					

* The product can only be tested at a concentration of 80% or less as some dilution is always produced by adding the test organisms and the interfering substance.

Justification for bridging studies

(For the confidential version of this table (including details on co-formulants), please refer to chapter 3.6 Confidential Annex of the PAR.)

Worst case products per *meta* SPC

For efficacy testing, the product Dip es SF can be seen as the worst case product for meta-SPCs 1 to 6 based on PVP iodine (1.16% PVP iodine), and the product calgodip D 1200 (0.14% iodine) can be seen as the worst case product for meta-SPCs 7, 8 and 9, based on iodine.

The justification is based on the product characteristics of Dip es SF and calgodip D 1200 containing the lowest active substance concentration within the product family (0.14% available iodine). Therefore they cover all other products with an equal or a higher active substance content concerning their biocidal effectivity.

Variations within the co-formulants are not expected to affect the efficacy (see explanation for different groups of co-formulants below). Therefore, the results of tests with Dip es SF and calgodip D 1200 can be regarded to cover all meta-SPCs.

Effects of surfactants in meta-SPCs 1-6

Dip es SF was identified as the worst-case product of meta-SPCs 1-6 as it contains the lowest concentration of available iodine (0.14%) and no surfactant.

Anionic and non-ionic surfactants are widely used in biocidal products as co-formulants. In general, the presence of a surfactant can improve the efficacy of a product as the surfactant decreases the surface tension resulting in a better wetting of the surface. Especially in the case of teat skin, which can be regarded as a rough surface, the presence of a surfactant in the disinfectant can, thus, be beneficial in terms of complying with the required log reductions within a short contact time. Moreover, there are no negative effects of (small amounts of anionic and non-ionic) surfactants towards microorganism described so far as anionic and non-ionic surfactants do not pass the cell membrane of microorganisms in a way cationic surfactants do.

Considering that Dip es SF has the lowest iodine concentration (0.14%) and no surfactant in the composition, it can be concluded that the other products of meta-SPC 1 to 6, which contain higher amounts of active substance (up to 0.5%) and/or amounts of surfactant, should be at least as effective as Dip es SF.

Effects of pH adjusters in meta-SPC 1-6

Buffering systems (pH adjusters) are widely used in biocidal products to buffer the formulation and to adjust/warrant a specific target pH (range). Dip es SF, the identified worst-case product of meta-SPCs 1 to 6 contains a buffer system. See for details 3.6 confidential annex.

Conclusion: The buffer system does not have an effect on efficacy and read-across to the worst-case product Dip es SF is justified.

Effects of alcohol ethoxylates (complexing agents) in meta-SPC 7, 8 and 9:
Calgodip D 1200 was identified as the worst-case product of meta-SPCs 7, 8 and 9 as it contains the lowest concentration of available iodine (0.14%) and the lowest concentration of alcohol ethoxylates.

Alcohol ethoxylates do not only belong to the class of complexing agents but also to a major class of non-ionic surfactants.

Effects of surfactants in meta-SPCs 7, 8 and 9:
Non-ionic and anionic surfactants are widely used in biocidal products as co-formulants. In general, the presence of a surfactant can improve the efficacy of a product as the surfactant decreases the surface tension resulting in a better wetting of the surface. Especially in the case of teat skin, which can be regarded as a rough surface, the presence of a surfactant in the disinfectant can, thus, be beneficial in terms of complying with the required log reductions within a short contact time. Moreover, there are no negative effects of (small amounts of non-ionic and anionic) surfactants towards microorganism described so far as non-ionic and anionic surfactants do not pass the cell membrane of microorganisms in a way cationic surfactants do.

Considering that calgodip D 1200 has the lowest iodine concentration (0.14%) and the lowest concentration of surfactant in the composition, it can be concluded that the other products of meta-SPCs 7, 8 and 9, which contain higher amounts of active substance (up to 0.54%) and higher amounts of surfactant, should be at least as effective as calgodip D 1200.

Pre-milking test conditions:
To support pre-milking claims of products in meta-SPC 4, meta-SPC 5, meta-SPC 6, meta-SPC 7 and meta-SPC 9, phase 2, step 1 suspension tests (EN1656, EN1657) have initially been performed using 10 g/L skimmed milk as soiling.

The Applicant was informed that testing with 10 g/L skimmed milk is not always the worst case compared to low (3 g/L) BSA soiling and that, therefore, tests with 3 g/L BSA cannot be waived without bridging studies.

The following bridging studies have been provided:
Phase 2, step 1 tests (EN1657) with the worst case products (Dip es SF and calgodip D 1200) and with the most difficult test organism, *Candida albicans,* at 30 sec contact time, in which efficacy with 10 g/L skimmed milk and 3 g/L BSA soiling was compared. These tests demonstrated that the pass results are the same independent of the interfering substance 3 g/L BSA or 1% skimmed milk. Therefore it can be accepted that for pre-milking teat disinfection under clean conditions data can be bridged with 1% skimmed milk as interfering substance in suspension tests.

In addition, phase 2 step 2 tests on artificial skin have been performed with 3 g/L BSA.

During the evaluation phase, the Applicant has dropped the pre-milking claims for meta-SPC 4, meta-SPC 5, meta-SPC 7 and meta-SPC 9. Pre-milking was only further supported for meta-SPC 6.

Conclusion on the efficacy of the product

The efficacy of the iodine-based teat disinfectants was investigated according to established methods by the European committee for standardization CEN/TC 216 WG 2 as laid down in EN 14885. Modifications to EN14885 have been made in accordance with Transitional guidance of the Biocidal Products Regulation PT1 – 4 (May 2016).

All tests were done at 30°C, the temperature of the skin. When the product is at a very low temperature at the start of the treatment (e.g. stored in animal housing at 10°C), the product might cool down the teat skin. This should be prevented because the product might be less efficacious at low temperature. Therefore, the following sentence will be added to the use instructions of the SPC: The products must be brought to temperatures above 20°C before use.

Post-milking disinfection in meta-SPCs 1-6
Efficacy was demonstrated with the worst case product for these meta-SPCs, Dip es SF. This product was tested under relevant conditions for this use (1% skimmed milk as interfering substance, temperature 30°C).
The product showed efficacy against bacteria (tested with test organisms relevant for teat disinfection) and yeasts, at the ready to use concentration in phase 2, step 1 suspension tests for the claimed contact time, 30 sec. These results were confirmed with tests with other products of these meta-SPCs.

However, in phase 2, step 2 simulated use test on artificial skin, efficacy against bacteria at the ready to use concentration was only demonstrated at 5 min contact time (log reduction >4).
Therefore, the contact time in the SPC is changed to a minimum of 5 min.

Post-milking disinfection in meta-SPCs 7, 8 and 9
Efficacy was demonstrated with the worst case product for these meta-SPCs, calgodip D 1200. This product was tested under relevant conditions for this use (1% skimmed milk as interfering substance, temperature 30°C).
The product showed efficacy against bacteria (tested with test organisms relevant for teat disinfection) and yeasts, at the ready to use concentration in phase 2, step 1 suspension tests for the claimed contact time, 30 sec. These results were confirmed with tests with other products of these meta-SPCs.

However, in phase 2, step 2 simulated use test on artificial skin efficacy against bacteria at the ready to use concentration was only demonstrated at 5 min contact time (log reduction >4).
Therefore, the contact time in the SPC is changed to a minimum of 5 min.

Pre-milking disinfection in meta-SPC 6
The Applicant initially intended to support pre-milking claims for meta-SPC 4, meta-SPC 5 and meta-SPC 6. During the evaluation phase, the Applicant decided to drop the pre-milking claims for meta-SPC 4 and meta-SPC 5. Pre-milking was only supported for meta-SPC 6.
Efficacy was demonstrated in suspension tests with the worst case product for these meta-SPCs, Dip es SF. This product was tested with 1% skimmed milk as interfering substance, for bacteria and yeast. For the use as pre-milking disinfectant tests should be performed with 3 g/L BSA as interfering substance. This was tested in a bridging study with yeast. This study showed that for this product and these test conditions, the interfering substances 1% skimmed milk and 3 g/L BSA gave similar results. Therefore, the studies on bacteria with 1% skimmed milk as interfering substance can be accepted

to demonstrate efficacy for pre-milking disinfection for these products.
The combined tests showed efficacy against bacteria (tested with test organisms relevant for teat disinfection) and yeasts, at the ready to use concentration in phase 2, step 1 suspension tests for the claimed contact time, 30 sec.

Phase 2, step 2 simulated-use test on artificial skin against bacteria were performed with Dip es SF under relevant conditions for this use (3 g/L BSA as interfering substance, temperature 30°C). The results of the tests were variable. At both 50% and 100% of the ready to use concentration the log reduction at 30 sec contact time was higher (lg 2.03) than at 60 sec (lg 1.66). It is normally expected that a longer contact time gives a higher log reduction. Since the results of these tests show the opposite, this test, which is still in development stage and not validated yet, might be to variable to draw conclusions from.
The log reduction was max lg 2.03 which is below the requested lg 3 (decision BPC efficacy WG decision when discussing this test protocol). Considering the variability in the test and the fact that the test is not validated yet, no conclusion can be drawn from these tests.

On request of the eCA NL, in order to support the pre-milking claim of meta-SPC 6, the Applicant performed further phase 2, step 2 tests with the relevant product of meta-SPC 6, Dip es Io-foam. Phase 2, step 2 simulated-use test on artificial skin against bacteria were performed with Dip es Io-foam under relevant conditions for this use (3 g/L BSA as interfering substance, temperature 30°C). For this ready to use product, the log reduction was lg 4.47 for 60 sec. contact time which is above the requested lg 3 (decision BPC efficacy WG decision when discussing this test protocol).
Based on the results of the phase 2, step 1 suspension tests and the phase 2, step 2 simulated-use test on artificial skin with 3 g/L BSA, it can be concluded that products within meta-SPC 6 will be sufficiently efficacious as pre-milking disinfectant on cleaned teats, against bacteria and yeasts after a contact time of 60 sec.

Pre-milking disinfection in meta-SPC 7 and 9
The Applicant initially intended to support pre-milking claims for meta-SPC 7 and 9. Since the eCA NL requested additional tests in order to support the pre-milking claim, the Applicant finally decided to drop the pre-milking claim for meta-SPC 7 and 9.

Additional justifications as requested by eCA on 12/11/2015

Justification of concentration range of products within BPF

CVAS`s teat disinfection product portfolio comprises products with a range of 0.14 – 0.54% available iodine. Although the products containing 0.14% available iodine may already be efficacious, the higher concentrated products are essential and need to be supported because of the following reasons:

- CVAS`s product portfolio (as supported by this BPR application) is a result of the historical market environment and actual market demands.
- Due to the fact that iodine is prone to degradation at high temperature, a "safety margin" in active substance content is advisable from an efficacy point of view.
- At present, it is not clear which iodine concentrations will be required to pass a future phase 2/step 2 test. From the preliminary results of a ring trial it may be concluded that only products with iodine concentrations in the higher range (i.e. 0.30 – 0.54% available) may pass the acceptance criteria of a future phase 2/step 2 test.

In summary, it is essential from both a marketability and efficacy point of view that the

teat disinfectants within the BPF have a broad range of active substance content.

The minimum of the concentration range for meta-SPC 2, meta-SPC 3, meta-SPC 4 and meta-SPC 8 has been set to a concentration lower than that of the product(s) within these meta-SPCs in order for the Applicant to be in the position to develop new products with lower active substance content. Given the controversial discussion about iodine residues in milk due to teat disinfection and the general concerns of the eCA NL regarding products with high iodine concentrations, this strategy seems to be advisable. For the extended meta-SPC ranges and theoretical products fitting within these ranges, read-across to the worst-case products Dip es SF and calgodip D 1200 containing only 0.14% avail. iodine is made (see justification for bridging studies above).

1.2.5.6 Occurrence of resistance and resistance management

As the mode of action is non-selective the occurrence of resistance against iodine is unlikely. Iodine based teat disinfectants are applied in practice at much higher active substance concentrations compared to the distinct lower MIC (minimal inhibitory concentration) values. Furthermore iodine has been used over 170 years as disinfectant for a variety of applications. No reduction in efficacy has been reported to the producers of iodine indicating that no development of resistant microorganisms has occurred so far (as cited in the CAR for iodine).

No management strategies have been developed since no occurrence of resistance has been observed. Nevertheless, it should be noted that iodine-based products are exclusively applied by professional users, in most cases as part of professional hygiene programs.

1.2.5.7 Known limitations

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

1.2.5.8 Evaluation of the label claims

The labels of the product family give clear instructions for preparing/cleaning teats before disinfection and for the application of the teat disinfectant. Instructions are given how the products have to be applied regarding the application procedure and the contact time. A contact time of at least 60 seconds before milking and 5 minutes after milking is recommended, in order to ensure sufficient time for the bactericidal and yeasticidal activity as it has been investigated in the efficacy test reports. Thus, it can be concluded that a sufficient efficacy is ensured by following the use instructions on the labels.
See the SPC and section 'Authorised use' of this PAR (section 1.1.4) for the authorised label claims and use instructions.

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

Not applicable. The products are not intended to be used in combination with other biocidal products.

1.2.6 Risk assessment for human health

1.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

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

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

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not causing severe damage or eye irritation.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products of meta-SPCs 1-6 and on read-across to a similar mixture for products of meta-SPCs 7-9 of the BPF.
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation"
IUCLID data point	Section 8.2, Eye irritation
Justification	Studies on potential eye damaging or eye irritating properties of the individual products pertaining to the biocidal product family (BPF) are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and chapter III, section 8.2 "Eye irritation" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." For all products pertaining to the BPF, the exact composition is known. For each of the individual components in the products, valid data on the intrinsic properties are available through state-of-the-art safety data sheets. There is no indication of synergistic effects between any of the components. Consequently, classification of the mixtures can be made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP) and testing of the components and/or of the biocidal products themselves is not required. According to the CLP principles, the individual products of meta-SPCs 1-6 do not need to be classified with respect to local effects on the eyes. According to the CLP principles, the maximum concentration of the alcohol ethoxylates would trigger a classification of the products within meta-SPCs 7-9 with respect to severe eye damage (Eye Dam. 1; H318). However, an eye irritation study performed with a similar mixture containing alcohol ethoxylate at a higher concentration compared to meta-SPCs 7-9 demonstrated the absence of an eye irritating/eye damaging potential. For details see the expert statement attached in section 13 of the IUCLID dossier.

	Based on the outcome of the read-across, the individual products of the BPF do not need to be classified with respect to local effects on the eyes. **Additional comments by Ctgb (eCA NL):** The eye irritation study is part of the Iodine EU dossier, which also includes the composition of the tested formulation in the eye irritation study. This information is available to the Ctgb (eCA NL). None of the other ingredients than already mentioned in the expert statement were classified for eye irritation. Therefore, eCA NL agrees with the applicant that the tested formulation of the eye irritation study could be considered worst case compared to the composition of meta-SPC 7-9. The tested formulation is not an eye irritant based on the outcome of the eye irritation study. Therefore, no classification for eye irritation is necessary for meta-SPC 7-9. Most important information from the expert statement is included in the confidential PAR.

Respiratory tract irritation

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

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

Skin sensitization

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

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

Respiratory sensitization (ADS)

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

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

Acute toxicity

Acute toxicity by oral route

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

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

Acute toxicity by inhalation

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

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

Acute toxicity by dermal route

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

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
IUCLID data point	Section 8.5.3, Acute toxicity: dermal
Justification	Studies on the potential acute dermal toxicity of the individual products pertaining to the biocidal product family (BPF) are not

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

Acute toxicity of product combinations

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

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Total iodine
Value(s)*	12% (evidence that dermal absorption is independent of concentration)
Justification for the selected value(s)	Read-across to similar tested mixtures.

** please include the concentration range(s) the values are applicable for, if relevant*

Data waiving	
Information requirement	Annex III of BPR, point 8.6 "Dermal absorption"
IUCLID data point	Section 8.6, Dermal absorption
Justification	Studies on the dermal absorption of iodine from the individual products pertaining to the biocidal product family (BPF) are not required. According to chapter III, section 8.6 "Information on dermal absorption" of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (version 1.1, Nov. 2014), dermal absorption can be estimated by extrapolation of experimental data obtained with a similar formulation. For the products of the BPF, dermal absorption can be assessed by read-across to two *in-vitro* human skin dermal absorption studies evaluated in the context of the active substance dossier on iodine (see CAR on iodine, including PVP-iodine, for PTs 1, 3, 4 and 22, 2013). These studies have been performed with an iodophor type 1-based biocidal product at an *in-use* concentration of 0.66% total iodine and a PVP-iodine based RTU product containing 0.26% total iodine. For both these tested products, a mean dermal absorption of 12% total iodine has been derived in accordance to the most recent EFSA guidance on dermal absorption (EFSA, 2012) and used for the human health exposure and risk assessments. The use concentrations covered by the scenarios as included in the assessment report on iodine in PTs 1, 3, 4 and 22 (SE, 2013) are in the range of 0.0055% to 2% available iodine. A justification for the validity and acceptability of a read-across and bridging to available dermal absorption data is provided in an expert statement attached to section 13 of the IUCLID dossier. Based on the conclusions drawn from the read-across, a dermal absorption value of 12% is used in the human health exposure assessments for all use scenarios of the products pertaining to the

	BPF. **Additional comments by Ctgb (eCA NL):** The dermal absorption study is part of the Iodine EU dossier, which also includes the composition of the tested formulations in the dermal absorption study. This information is available to the Ctgb (eCA NL). The other ingredients in the BPF, than that were already mentioned in the expert statement, were comparable to the tested formulations. Therefore, eCA NL agrees with the applicant that read-across to the tested formulations as included in the CAR is possible and a value of 12% will be used for dermal absorption in the risk assessment of the BPF. The argumentation of the applicant via its consultant was provided during discussion of dossier and included in the discussion table of CVAS (WGVI 2017). The documents used for the discussion are uploaded in R4BP3, including a textual adaption as agreed upon by the WG. It is noted that in Table 1 included in the argumentation ranges within +/-25% w/v are included for the active substance. This is not in accordance to the EFSA dermal absorption guidance 2012. EFSA guidance only includes a range within +/-25% w/v to evaluate similarity for co-formulants, synergist and safeners. However, the WG agreed on dermal absorption of 12 % for the biocidal product family.

Available toxicological data relating to

Other endpoints

No other toxicological effects (e.g. CMR, STOT RE, STOT SE) are anticipated from the biocidal products.

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

For acetic acid, an 8-hour TWA of 10 ppm (25 mg/m^3) and STEL (15 min) of 20 ppm (50 mg/m^3) has been recommended by the Scientific Committee on Occupational Exposure Limits (SCOEL, June 2012). Thus, acetic acid is to be considered a substance of concern (SoC) according to the CA document "CA-Nov14-Doc.5.11 - SoC guidance_final.doc".

However, as these limit values are much higher than the OEL for iodine (1mg/m^3), the risk assessment for iodine will also cover the risk resulting from the exposure to the SoC acetic acid. No separate risk assessment for acetic acid has to be performed.

A detailed systematic evaluation of all components of the BPF, performed according to Article 3(f) of Regulation (EU) No. 528/2012 and CA document "CA-Nov14-Doc.5.11 - final" ("Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products"), is attached to section 13 of the IUCLID dossier.

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

The SoCs have been assessed based on the breakdown of the starting materials to the individual substances, i.e. on "pure" substances present in the final formulations. The result of this assessment is provided in the chapter "Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)" above.
Consequently, additional toxicological data on SoC-containing mixtures, i.e. testing of the SoC-containing mixtures and/or of the biocidal products themselves, is not required.

Other

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

Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product
Application of the iodine-based teat disinfection products pertaining to the BPF may lead to iodine residues in milk. The assessment of potential iodine residues in milk is summarized in the statement "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group which can be found attached in section 13 of the IUCLID dossier.

Industrial processing and/or domestic preparation of milk such as pasteurization or fermentation may lead to a reduction of the initial iodine levels in raw milk (see discussion paper for details). However, there is no indication that during processing toxicologically significant degradation products of iodine arise in the pasteurized milk and dairy products which may require a separate risk assessment.

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

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

1.2.6.2 Exposure assessment

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

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

n.a.: not applicable

Explanatory note:

The exposure assessments are based on model calculations using models and default values from the HEAdhoc Recommendation no. 13 (Jan. 2017) – "Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)".

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

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

- Pre-milking disinfection
    - Manual foaming using a foam cup (applies to meta-SPC 6)
- Post-milking disinfection
    - Manual dipping using a dip cup (applies to meta-SPCs 1-5 and 7 - 9)
    - Automatic dipping (applies to meta-SPCs 1-5 and 7 - 9)
    - Manual foaming using a foam cup (applies to meta-SPCs 6, 7 and 9)
    - Automatic foaming (applies to meta-SPCs 6, 7 and 9)
    - Manual spraying using a trigger sprayer (applies to meta-SPCs 4, 5, 7 and 9)
    - Manual spraying using an electronic sprayer (applies to meta-SPCs 4, 5, 7 and 9)

- Automated spraying by robot (applies to meta-SPCs 4, 5, 7 and 9)

- Pre- and post-milking disinfection

  - Manual foaming using a foam cup (applies to meta-SPC 6)

General considerations:

The disinfection by manual or automated dipping, foaming or spraying takes place indoor after each milking, i.e. 1-3 times per day. Only in case of manual foaming, disinfection takes place before and/or after milking, i.e. 2-6 times per day.
In line with HEAdhoc Recommendation no. 13 (Jan. 2017), it is considered that the default value for a dairy cow herd size is 100 animals (ESD for PT3, Jan. 2012) and that dairy cows are regularly milked twice per day. Taking into account the lactation period for dairy cows (i.e. 270-300 days), 82 milk producing cows from a herd size of 100 dairy cows are milked per day (100 cows x 300/365 = 82 cows). For higher animal numbers or more milkings per day, an additional milker is needed.

The products within the BPF are ready-to-use (RTU) products. The RTU products for pre- and/or post-milking disinfection contain available iodine and iodide (from potassium iodide or PVP-iodine) at concentrations in the range of 0.14-0.54% and 0.05-0.42%, respectively (equivalent to 0.19%-0.84% total iodine).

Calculations for the different scenarios as presented in the following sections are only performed for worst-case iodine concentrations within the BPF, taking into account total iodine concentrations. These worst-case concentrations are determined per meta-SPC and are as follows:

- Meta-SPC 1 (Dip es barriere containing 0.19% total iodine)
  - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)

- Meta-SPC 2 (Dip es Io-film containing 0.40% total iodine)
  - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)

- Meta-SPC 3 (Dip es barriere S containing 0.40% total iodine and Dip es barriere RS containing 0.67% total iodine)
  - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)

- Meta-SPC 4 (Dip es silver containing 0.40% total iodine)
  - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)
  - Manual and automated spraying, post-milking: covered by the worst-case concentration of 0.72% total iodine (meta-SPC 9)

- Meta-SPC 5 (Dip es SF containing 0.19% total iodine)
  - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)

    - Manual and automated spraying, post-milking: covered by the worst-case concentration of 0.72% total iodine (meta-SPC 9)

- Meta-SPC 6 (Dip es Io-foam containing 0.19% total iodine)
    - Manual foaming, pre-milking: worst-case concentration of 0.19% total iodine
    - Manual and automated foaming, post-milking: worst-case scenario "manual and automated dipping, post-milking" (meta-SPC 8)
    - Manual foaming, pre- plus post-milking: worst-case concentration of 0.19% total iodine

- Meta-SPC 7 (calgodip D 1200 containing 0.29% total iodine)
    - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)
    - Manual and automated foaming, post-milking: covered by the worst-case scenario "manual and automated dipping, post-milking" (meta-SPC 8)
    - Manual and automated spraying, post-milking: worst-case concentration of 0.56% total iodine

- Meta-SPC 8 (calgodip D 3000 Film containing 0.64% total iodine and calgodip D 5000 containing 0.84% total iodine)
    - Manual and automated dipping, post-milking: worst-case concentration of 0.84% total iodine

- Meta-SPC 9 (calgodip D 3000 containing 0.72% total iodine)
    - Manual and automated dipping, post-milking: covered by the worst-case concentration of 0.84% total iodine (meta-SPC 8)
    - Manual and automated foaming, post-milking: covered by the worst-case scenario "manual and automated dipping, post-milking" (meta-SPC 8)
    - Manual and automated spraying, post-milking: worst-case concentration of 0.72% total iodine

As explained in the statement on dermal penetration, read across from the *in vitro* human skin dermal penetration study performed with products containing total iodine at concentrations in the range of 0.26-0.66% is possible. The dermal penetration value of 12% determined for the mentioned concentration range can be read across to all products within the BPF.

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

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

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

Note of the eCA: Inhalation exposure was a point of discussion at the WGIV for two other UA dossiers, and this issue was closed in ad hoc follow-up (secure WebEx discussion 25-10-2017). The following was concluded: *The ad hoc follow-up members agreed that in these two applications inhalation exposure to vapours could be considered as negligible and therefore inhalation exposure to vapours does not need to be assessed. The argumentation provided by the applicants should be included in the PAR.*
The argumentation as discussed in WGIV was provided by the applicant during discussion of dossier and included in the discussion table of CVAS (WGVI 2017).
This information is included in annex 2.2.

List of scenarios

Summary table: scenarios for pre- and/or post-milking disinfection by dipping, foaming or spraying			
Scenario number	**Scenario**	**Primary exposure** **Description of scenario**	**Exposed group**
1.1	Mixing and loading of RTUs for dip / foam cup or trigger sprayer	Preparation of dip / foam cups: The product (RTU) is filled undiluted into the reservoir of a dip /foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip / foam cup above the reservoir which is then ready for dipping/foaming. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip / foam cup or of a trigger sprayer is done analogously.	professionals
1.2	Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device	A can containing the RTU product is opened and a suction tube of the electronic sprayer, automated dipping/foaming system or robotic milking device is inserted. Empty cans are replaced by new ones.	professionals
2.1	Application of teat disinfectant by manual dipping/foam	Before and/or after milking, the dip / foam cup prepared as described in scenario 1.1 is put over each teat from below making sure that the full length of each teat is immersed into the disinfectant.	professionals
2.2	Application of teat disinfectant by automated dipping/foaming-system	This scenario replaces scenario 2.1 in case of automated dipping/foaming. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with dip/foam.	No exposure
2.3	Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer	This scenario replaces scenarios 2.1 and 2.2 in case of spray application. Before and/or or after milking, the teats are sprayed with the disinfectant using a trigger sprayer or electronic sprayer making sure that each teat is covered with the disinfectant.	professionals
2.4	Application of teat disinfectant by robot with automatic sprayer	This scenario replaces scenarios 2.1 to 2.3. After milking, the disinfectant is sprayed automatically onto teats from a cluster arm.	No exposure

3.1	Cleaning of teats by wiping with cloth: removal of freshly applied product	The teats which have been treated with a disinfectant shortly before are carefully cleaned by wiping with a dry cloth immediately before milking.	professionals
3.2	Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment	Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a post-milking treatment. The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.	Negligible exposure
3.3	Cleaning of teats by robot: removal of dried residues from post-milking treatment	This scenario replaces scenario 3.2 if teats are cleaned with robot. Before each milking, the teats are cleaned by robot with automatic brushes.	No exposure
4.1	Cleaning of equipment such as dip/foam cups, trigger sprayer after use	After application, the reservoir is emptied and the entire dip/foam or spray equipment is cleaned with water. Only a small amount of diluted product will remain in the application equipment; however this will be highly diluted by the wash-water.	professionals
4.2	Rinsing of automated dipping/foaming-system	This scenario replaces scenario 4.1 if automated dipping/foaming-system is used. Every liner of the automated dipping/foaming-system is thoroughly rinsed with water and blown out with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated and, therefore, there is no human exposure.	No exposure
4.3	Rinsing of electronic sprayer	This scenario replaces scenarios 4.1 and 4.2 if an electronic sprayer is used. After disinfection, the sprayer is flushed with water: the sprayer is operated for few seconds with water instead of the disinfectant. Exposure is considered negligible.	Negligible exposure

Industrial exposure

Industrial exposure is not relevant.

Professional exposure

Scenario [1.1]: Mixing and loading of RTUs for dip/foam cup or trigger sprayer by manual pouring

Description of Scenario [1.1] - Mixing and loading of RTUs for dip/foam cup or trigger sprayer by manual pouring
Preparation of dip/foam cups: The product (RTU) is filled undiluted into the reservoir of a dip/foam cup. By squeezing the reservoir, the disinfectant is pumped into the dip/foam cup above the reservoir which is then ready for dipping. Preparation of a trigger sprayer: The product (RTU) is filled undiluted into the reservoir of a sprayer. Re-filling of a dip / foam cup or of a trigger sprayer is done analogously. According to HEAdhoc Recommendation no. 13 (Jan. 2017) – "Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3)" - , Mixing and loading model 4 is recommended for repeated loading of small quantities. For dermal (hand) exposure, the total amount of the required solution that is needed per day is of importance. Automatically, cows are miked three times a day (i.e. manually cows are milked twice a day), treated either pre- or post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 3 times a day = 15 ml. Considering 82 cows, this results in a total amount of product per day of 15 ml x 82 cows = 1.2 L product/day. However, for metaSPC6 (0.19% total iodine) pre- plus post milking treatments is applied for, therefore the total amount used for treatment is therefore: 5ml product x 6 times a day = 30 ml. Considering 82 cows, this results in a total amount of product per day of 30 ml x 82 cows = 2.5 L product/day. For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used for the evaluation mixing and loading. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. The model covers all relevant mixing and loading tasks performed by a worker on an 8-h working day. Thus, re-filling of the equipment with the RTU product is covered within the mixing and loading step and does not need to be assessed separately.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking, post-milking and pre- plus post milking treatments	0.19%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.56%

	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.72%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.84%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative value for hand exposure (for handling product volumes of 5L)	0.2 mL/treatment
	No PPE	0% protection
Tier 2	Gloves	90% protection

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

In the following, the results of the calculations are provided for scenario 1.1 performed once a day when using a **RTU product containing 0.19%, 0.56%, 0.72% and 0.84% total iodine**.

The calculation sheets are provided in Annex 3.2

Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1] – M/L model 4 – 0.19% total iodine	Tier 1/ none	-	7.60E-04	-	7.60E-04
	Tier 2 / gloves	-	7.60E-05	-	7.60E-05
Scenario [1.1] – M/L model 4 – 0.56% total iodine	Tier 1/ none	-	2.24E-03	-	2.24E-03
	Tier 2 / gloves	-	2.24E-04	-	2.24E-04
Scenario [1.1] – M/L model 4 – 0.72% total iodine	Tier 1/ none	-	2.88E-03	-	2.88E-03
	Tier 2 / gloves	-	2.88E-04	-	2.88E-04
Scenario [1.1] – M/L model 4 – 0.84% total iodine	Tier 1/ none	-	3.36E-03	-	3.36E-03
	Tier 2 / gloves	-	3.36E-04	-	3.36E-04

Further information and considerations on scenario [1.1] – Mixing and loading of RTUs for dip / foam cup or trigger sprayer by manual pouring

Not relevant.

Scenario [1.2]: Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device

Description of Scenario [1.2] - Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device		
This scenario replaces scenario 1.1 if electronic sprayer or robotic milking device (for automated spraying) is used. A can containing the RTU product is opened and a suction tube of the electronic sprayer, automated dipping/foaming system or robotic milking device is inserted. The exposure duration of 1 min per day for RTU is used. According to the HEAdhoc Recommendation no. 13 (Jan. 2017), the RISKOFDERM toolkit for connecting lines is recommended for automated mixing and loading with an indicative value of 0.92 mg/min for dermal exposure. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. Connecting transfer lines is performed once a day. Thus, re-filling of the equipment with the RTU product is covered within the mixing and loading step and does not need to be assessed separately.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.19%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.56%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.72%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.84%
	Dermal penetration	12%
	Body weight	60 kg
	Indicative value for dermal exposure	0.92 mg/min
	Exposure duration	1 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] – Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device (for automated spraying)

In the following, the results of the calculations are provided for scenario 1.2 performed once a day when using a **RTU product containing 0.19%, 0.56%, 0.72% and 0.84% total iodine**.

The calculation sheets are provided in Annex 3.2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – RISKOFDERM Toolkit, Connecting lines – 0.19% total iodine	Tier 1/ none	-	3.50E-06	-	3.50E-06
	Tier 2/ gloves	-	3.50E-07	-	3.50E-07
Scenario [1.2] – RISKOFDERM Toolkit, Connecting lines – 0.56% total iodine	Tier 1/ none	-	1.03E-05	-	1.03E-05
	Tier 2/ gloves	-	1.03E-06	-	1.03E-06
Scenario [1.2] – RISKOFDERM Toolkit, Connecting lines – 0.72% total iodine	Tier 1/ none	-	1.32E-05	-	1.32E-05
	Tier 2/ gloves	-	1.32E-06	-	1.32E-06
Scenario [1.2] – RISKOFDERM Toolkit, Connecting lines – 0.84% total iodine	Tier 1/ none	-	1.55E-05	-	1.55E-05
	Tier 2/ gloves	-	1.55E-06	-	1.55E-06

Further information and considerations on scenario [1.2] – Mixing and loading of electronic sprayer, automated dipping/foaming-system or robotic milking device

Not relevant.

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

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

Scenario [2.2]: Application of teat disinfectant by automated dipping/foaming

Description of Scenario [2.2] - Application of teat disinfectant by automated dipping/foaming-system
This scenario replaces scenario 2.1 in case of automated dipping/foaming. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the clawpiece. The teats are coated with dip/foam when the teat cup is withdrawn. No exposure of professionals occurs. This scenario was not considered in the CAR.

Scenario [2.3]: Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

Description of Scenario [2.3] - Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

This scenario replaces scenarios 2.1 and 2.2 in case of manual spray application.

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

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

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

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

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

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.56%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.72%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m^3/h (0.021 m^3/min)
	Exposure duration	13.7 min
	Indicative value for dermal exposure	36.1 mg/min
	Indicative value for inhalation exposure (aerosol)	10.5 mg/m^3
	No PPE	0% protection
Tier 2	Gloves, coverall and chemical resistant boots	90% protection

Calculations for Scenario [2.3] - Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

In the following, the results of the exposure calculations of scenario 2.3 are provided for 82 animals disinfected after each milking, i.e. twice a day when using a **RTU product containing 0.56% or 0.72% total iodine**.

The calculation sheets are provided in Annex 3.2

Exposure scenario	Tier / PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [2.3] – Consumer spraying and dusting model 2. Hand-held trigger spray – 0.56% total iodine	Tier 1/ none	5.58E-04	1.40E-02	-	1.46E-02
	Tier 2/ Gloves	5.58E-04	4.07E-03	-	4.63E-03
Scenario [2.3] – Consumer spraying and dusting model 2. Hand-held trigger spray – 0.72% total iodine	Tier 1/ none	7.18E-04	1.80E-02	-	1.87E-02
	Tier 2/ Gloves, coverall and chemical resistant boots	7.18E-04	1.80E-03	-	2.52E-03

Further information and considerations on scenario [2.3] - Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer: Local exposure concentration of iodine in air (for 0.56% or 0.72% total iodine)

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer spraying and dusting model 2, 2. Hand-held trigger spray, 0.56% total iodine	5.88E-02
Scenario [2.2] – Consumer spraying and dusting model 2, 2. Hand-held trigger spray, 0.72% total iodine	7.56E-02

Scenario [2.4]: Application of teat disinfectant by robot with automatic sprayer

Description of Scenario [2.4] - Application of teat disinfectant by robot with automatic sprayer
This scenario replaces scenarios 2.1 to 2.3 in case of spray application by robot. After robotic milking, the disinfectant is sprayed automatically onto teats from a cluster arm. No exposure of professionals occurs. This scenario was not considered in the CAR.

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

Description of Scenario [3.1] - Cleaning of teats by wiping with cloth: removal of freshly applied product
The teats which have been treated with a disinfectant shortly before are carefully cleaned by wiping with a dry cloth immediately before milking. In the CAR, the TNsG 2002 model "surface disinfection model 2" was used for assessing the cleaning of teats during pre-milking disinfection. It is indicated by the applicant that this model does not adequately describe the task "cleaning of teats", since it refers to "washing and wiping floors with mob, bucket and wringer", a scenario for which considerably higher exposure is expected than for cleaning of teats. Furthermore, the model does not provide any indicative value for inhalation exposure nor for dermal exposure to hands. On the other hand, the indicative value for the body provided in the model is not relevant at all for the cleaning of teats with cloth. To cover this scenario, exposure estimates were made according to HEAdhoc Recommendation no. 13 (Jan. 2017). As a worst-case, based on the Disinfectant Products Fact Sheet (RIVM report 320005003/2006), it is assumed that 0.1% of the amount of the RTU on the surface area (here: the teats and a part of the udder of the cow with 44 cm^2/teat and 176 cm^2/cow) contacts the palm of the hands. To calculate the amount of the RTU on the surface area, the layer thickness approach is considered appropriate, i.e. 44 cm^2/teat x 4 teats x 0.01 cm x number of cows. Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant.

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking treatments	0.19%
	Dermal penetration	12%

	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Surface area of an average teat	44 cm^2
	Surface area per cow (with 4 teats)	176 cm^2
	Percentage of RTU in contact with hands (palms)	0.1%
	No PPE	0% protection
Tier 2	Gloves	90% protection

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

In the following, the results of the calculations for the scenario 3.1 are provided for 82 animals disinfected before each milking, i.e. twice a day when using a **RTU product containing 0.19% total iodine**.

The calculation sheets are provided in Annex 3.2

Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [3.1] – generic approach acc. to HEAdhoc 13 – 0.19% total iodine	Tier 1/ none	-	1.10E-03	-	1.10E-03
	Tier 2/ Gloves	-	1.10E-04	-	1.10E-04

Further information and considerations on scenario [3.1] - Cleaning of teats by wiping with cloth: removal of freshly applied product

Not relevant.

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

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

Cleaning of teats by wiping with a dry cloth before milking is only relevant if the cows have received a post-milking treatment.
The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.

Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure.

This work step was not considered in the CAR.

Scenario [3.3]: Cleaning of teats by robot

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

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

Description of Scenario [4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use
After application, the reservoir is emptied and the entire dip / foam or spray equipment is cleaned with water. A small amount of diluted product will remain in the application equipment; however this will be highly diluted by the wash-water. Therefore, it is concluded that exposure during cleaning of application equipment is lower in comparison with the exposure during mixing and loading and application operations. Due to the lack of an appropriate exposure model for the scenario "cleaning of equipment", the model RISKOFDERM Toolkit, Connecting lines is used as a surrogate model according to HEAdhoc Recommendation no. 13 (Jan. 2017). Inhalation exposure is not assessed, since aerosol formation is not expected. In addition, as the active substance is complex-bound, evaporation is not considered relevant. The duration for this task is considered to be 5 min. Experience from practice supports that the professional milker cleans the equipment at

the end of the working day, i.e. only once per day.		
	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in RTU considered for assessing pre-milking, post-milking and pre- plus post milking treatments	0.19%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.56%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.72%
	Total iodine (available iodine and iodide) in RTU considered for assessing post-milking treatments	0.84%
	Dermal penetration	12%
	Body weight	60 kg
	Exposure duration	5 min
	No PPE	0% protection
Tier 2	Gloves	90% protection

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

In the following, the results of the calculations for the scenario 4.1 are provided for twice a day when using a **RTU product containing 0.19%, 0.56%, 072% and 0.84% total iodine.**

The calculation sheets are provided in Annex 3.2

Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4.1] – RISKOFDERM Toolkit, Connecting lines – 0.19% total iodine	Tier 1/ none	-	1.75E-05	-	1.75E-05
	Tier 2/ Gloves	-	1.75E-06	-	1.75E-06

Scenario [4.1] – RISKOFDERM Toolkit, Connecting lines – 0.56% total iodine	Tier 1/ none	-	5.15E-05	-	5.15E-05
	Tier 2/ Gloves	-	5.15E-06	-	5.15E-06
Scenario [4.1] – RISKOFDERM Toolkit, Connecting lines – 0.72% total iodine	Tier 1/ none	-	6.62E-05	-	6.62E-05
	Tier 2/ Gloves	-	6.62E-06	-	6.62E-06
Scenario [4.1] – RISKOFDERM Toolkit, Connecting lines – 0.84% total iodine	Tier 1/ none	-	7.73E-05	-	7.73E-05
	Tier 2/ Gloves	-	7.73E-06	-	7.73E-06

Further information and considerations on scenario [4.1] - Cleaning of equipment such as dip/foam cups, trigger sprayer after use

Not relevant.

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

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

Scenario [4.3] - Rinsing of electronic sprayer

Description of Scenario [4.3] - Rinsing of electronic sprayer

This scenario replaces scenario 4.1 and 4.2 if an electronic sprayer is used.

After disinfection, the sprayer is flushed with water: the sprayer is operated for few seconds with water instead of the disinfectant. Exposure is considered negligible.

This scenario was not considered in the CAR.

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

Explanatory note:

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

- Pre-milking disinfection using RTUs (0.19% total iodine)
    - Manual foaming using a foam cup (applies to meta-SPC 6.)
- Post-milking disinfection using RTUs (0.56%, 0.72% or 0.84% total iodine)
    - Manual dipping/foaming using a dip/foam cup (Dip applications apply to meta-SPCs 1-5 and 7 -9. Foam applications apply to meta-SPCs 6, 7 and 9.)
    - Automated dipping/foaming (Dip applications apply to meta-SPCs 1-5 and 7 - 9. Foam applications apply to meta-SPCs 6, 7 and 9.)
    - Manual spraying using a trigger sprayer (applies to meta-SPCs 4, 5, 7 and 9)
    - Manual spraying using an electronic sprayer (applies to meta-SPCs 4, 5, 7 and 9)
    - Automated spraying by robot (applies to meta-SPCs 4, 5, 7 and 9)
- Pre- and post-milking disinfection using RTUs (0.19% total iodine)
    - Manual foaming using a foam cup (applies to meta-SPC 6.)

Pre-milking disinfection of 82 animals twice a day

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

- RTU: 0.19% total iodine

The scenarios considered are mixing and loading of RTUs [1.1], application [2.1], cleaning of teats before milking: removal of freshly applied product [3.1] and cleaning of equipment [4.1].

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Manual foaming – RTU (0.19% total iodine) Scenarios [1.1; 2.1; 3.1; 4.1]	Tier 1/ none	-	1.87E-03	1.87E-03
	Tier 2/ Gloves	-	1.87E-04	1.87E-04

Post-milking disinfection of 82 animals twice a day

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

- RTU: 0.56%, 0.72% or 0.84% total iodine

The scenarios considered are RTUs [1.1 or 1.2], cleaning of teats before milking: removal of dried product [3.2 or 3.3], application [2.1, 2.2, 2.3 or 2.4] and cleaning of equipment [4.1, 4.2 or 4.3].

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Manual dipping / foaming – RTU (0.84% total iodine) Scenarios [1.1; 2.1; 3.2; 4.1]	Tier 1/ none	-	3.44E-03	3.44E-03
	Tier 2/ gloves	-	3.44E-04	3.44E-04

Automated dipping/foaming - RTU (0.84% total iodine) Scenarios [1.2; 2.2; 3.3; 4.2]	Tier 1/ none	-	1.55E-05	1.55E-05
	Tier 2/ Gloves	-	1.55E-06	1.55E-06
Manual spraying using a trigger sprayer – RTU (0.56% total iodine) Scenarios [1.1; 2.3; 3.2; 4.1]	Tier 1/ none	5.58E-04	1.63E-02	1.69E-02
	Tier 2/ Gloves	5.58E-04	4.30E-03	4.86E-03
Manual spraying using an electronic sprayer – RTU (0.56% total iodine) Scenarios [1.2; 2.3; 3.2; 4.3]	Tier 1/ none	5.58E-04	1.40E-02	1.46E-02
	Tier 2/ Gloves	5.58E-04	4.08E-03	4.63E-03
Automated spraying by robot - RTU (0.56% total iodine) Scenarios [1.2; 2.4; 3.3; 4.2]	Tier 1/ none	-	1.03E-05	1.03E-05
	Tier 2/ Gloves	-	1.03E-06	1.03E-06
Manual spraying using a trigger sprayer – RTU (0.72% total iodine) Scenarios [1.1; 2.3; 3.2; 4.1]	Tier 1/ none	7.18E-04	2.10E-02	2.17E-02
	Tier 2/ Gloves, coverall and chemical resistant boots	7.18E-04	2.10E-03	2.81E-03
Manual spraying using an electronic sprayer – RTU (0.72% total iodine) Scenarios [1.2; 2.3; 3.2; 4.3]	Tier 1/ none	7.18E-04	1.81E-02	1.88E-02
	Tier 2/ Gloves, coverall and chemical resistant boots	7.18E-04	1.80-03	2.52E-03
Automated spraying by robot - RTU	Tier 1/ none	-	1.32E-05	1.32E-05

(0.72% total iodine) Scenarios [1.2; 2.4; 3.3; 4.2]	Tier 2/ Gloves	-	1.32E-06	1.32E-06

Pre- and post-milking disinfection of 82 animals twice a day

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

- RTU: 0.19% total iodine total iodine

The scenarios considered are mixing and loading of RTUs [1.1], cleaning of teats: removal of dried product [3.2], application [2.1 or 2.3], cleaning of teats before milking: removal of freshly applied product [3.1], application [2.1] and cleaning of equipment [4.1].

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Manual foaming – RTU (0.19% total iodine) Scenarios [1.1; 3.2; 2.1; 3.1; 2.1; 4.1]	Tier 1/ none	-	1.87E-03	1.87E-03
	Tier 2/ Gloves	-	1.87E-04	1.87E-04

Non-professional exposure

Non-professional exposure is not relevant.

Exposure of the general public

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

Monitoring data

Concerning human exposure, no monitoring data are available.

Concerning residues in milk, several publications are available:
For the evaluation of dietary exposure, reference to the residue studies summarized and discussed in the CAR and to a new residue study (O`Brien, 2013) is made. For the purpose of product authorization, these studies have been (re-)assessed with a focus on

application regimes relevant for IRG Members (including CVAS) and summarized in the "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" of 29 June 2015.

Dietary exposure

All existing teat disinfection products of the BPF are ready-to-use (RTU) products.

The PVP-iodine based "Dip es" products pertaining to meta-SPCs 1-6 contain available iodine at a concentration of 0.14 - 0.50%. Total iodine, as sum of available iodine and iodide from PVP-iodine, is calculated to be 0.19 – 0.67%.

The "calgodip D" products based on pure iodine and pertaining to meta-SPCs 7, 8 and 9 contain available iodine at a concentration of 0.14 – 0.54%. Total iodine, as sum of available iodine and iodide from potassium iodide (used as solubilizing agent), is calculated to be 0.29 – 0.84%

In the following table "List of scenarios", all 9 relevant intended use scenarios are listed.

In order to avoid lengthy and redundant calculation tables, the dietary exposure assessment is limited to the worst-case use scenarios of the BPF. The same applies to the livestock exposure assessment.

Identification of worst-case use scenarios

As a general principle it can be assumed that exposure of animals, and thus residues in milk and animal safety, are directly related to application rates, i.e. the amount of product applied to the animal`s teats. In this respect, manual application scenarios are considered to be associated with higher application rates when compared to automated spraying scenarios.

Regarding the application methods, spraying is considered worst-case when compared to dipping or foaming applications.

Based on these considerations, the following worst-case scenarios have been identified for the 9 meta-SPCs of the BPF and assessed concerning their dietary risk. The scenarios are highlighted in bold in the table "List of scenarios" below:

Scenario 1 (= **Use # 1.1**) pre-milking teat-disinfection
manual foaming
available iodine: 0.14%, total iodine: 0.19%
worst-case product: Dip es Io-foam

Scenario 2 (= **Use # 1.2**) post-milking teat-disinfection
manual dipping
available iodine: 0.54%, total iodine: 0.84%
worst-case product: calgodip D 5000

Scenario 4 (= **Use # 1.4**) post-milking teat-disinfection
manual spraying using a trigger sprayer
available iodine: 0.14%, total iodine: 0.56%
worst-case product: calgodip D 1200

Scenario 4 (= **Use # 1.4**) post-milking teat-disinfection
manual spraying using a trigger sprayer
available iodine: 0.34%, total iodine: 0.72%
worst-case product: calgodip D 3000

Scenario 9 (= **Use # 1.9**) pre- and post-milking teat-disinfection
manual foaming
available iodine: 0.14%, total iodine: 0.19%
worst-case product: Dip es Io-foam

Dietary exposure is assessed for adults and children.

Residue definitions
At the time of dossier submission, there is no residue definition for the intended biocidal use: Use # 1 – Teat disinfection of milkable animals. For information on the non-biocidal use of the active substance, please refer to the table below.

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
1.	**Animal husbandry**	**pre-milking teat-disinfection**	Iodine in milk
		manual foaming	
		concerns: meta-SPC 6	
2.	**Animal husbandry**	**post-milking teat-disinfection**	Iodine in milk
		manual dipping	
		concerns: meta-SPCs 1, 2, 3, 4, 5, 7, 8 and 9	
3.	Animal husbandry	post-milking teat-disinfection	Iodine in milk
		manual foaming	
		concerns: meta-SPCs 6, 7 and 9	
4.	**Animal husbandry**	**post-milking teat-disinfection**	Iodine in milk
		manual spraying (trigger sprayer)	
		concerns: meta-SPCs 4, 5, 7 and 9	
5.	Animal husbandry	post-milking teat-disinfection	Iodine in milk
		manual spraying (electronic sprayer)	
		concerns: meta-SPCs 4, 5, 7 and 9	
6.	Animal husbandry	post-milking teat-disinfection	Iodine in milk
		automated dipping	
		concerns: meta-SPCs 1, 2, 3, 4, 5, 7, 8 and 9	
7.	Animal	post-milking teat-disinfection	Iodine in milk

	husbandry	automated foaming	
		concerns: meta-SPCs 6, 7 and 9	
8.	Animal husbandry	post-milking teat-disinfection	Iodine in milk
		automated spraying by robot	
		concerns: meta-SPCs 4, 5, 7 and 9	
9.	**Animal husbandry**	**pre- and post-milking teat-disinfection**	Iodine in milk
		manual foaming	
		concerns: meta-SPC 6	

[1] e.g. animal husbandry, food industry, professional use, residential use.
[2] e.g. chicken, milk, beer

Information of non-biocidal use of the active substance

Residue definitions
Please refer to the following table for information on MRLs and relevant regulations.

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s)[2]**
1.	Veterinary use	Teat-disinfection with veterinary claim (reduction of mastitis)	"no MRL required" for all target tissues according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009 [Based on an evaluation of the committee for veterinary medicinal products were it was agreed that it would be inappropriate to elaborate MRLs for iodine.]; see NOTE below the table for additional information on MRLs for iodine.
2.	Food additives	Fortification of food (iodised salt)	National regulations in place; 10-75 mg/kg salt (majority of values in the range of 15-30 mg/kg) according to EFSA NDA Panel, 2014, Scientific Opinion on Dietary Reference Values for iodine, EFSA Journal 2014; 12(5);3660 (doi:10.2903/j.efsa.2014.3660)

3.	Feed additives	Supplementation of animal feed	Dairy cows: 5 mg I/kg of complete feedingstuff according to Commission Regulation (EC) No 1459/2005 of 8 Sept. 2005 2 mg I/kg recommended according to EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Scientific opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all animal species […], EFSA Journal 2013; 11(2):3099 (doi:10.2903/j.efsa.2013.3099)

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

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

NOTE: In the Assessment Report on iodine (including PVP-iodine) and Commission Implementing Regulation (EU) No 94/2014 approving iodine (including PVP-iodine) for use in PT 1, 3, 4 and 22 it was concluded that the "*need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council or Regulation (EC) No 396/2005 of the European Parliament and of the Council shall be verified […]"* for products that may lead to residues in food or feed.

The Iodine Registration Group (IRG) is of the opinion that, in general, MRLs need to be set on active substance level triggered by human safety concerns.

Despite this conclusion, the IRG has been confident that in the framework of national product authorisations a re-assessment of MRLs for iodine would not be needed for the following reasons:

- No MRLs are required for iodine and iodine inorganic compounds such as iodophors (including polyvinylpyrrolidone iodine) for all food producing species and all target tissues according to *Regulation (EC) No 470/2009 of the European Parliament and of the Council and Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin*: Although the direct treatments of cows with iodine-containing veterinary hygiene products may lead to residues in milk, the European Agency for the Evaluation of Medicinal Products (EMA) concluded in their summary report on iodine that it would be inappropriate to elaborate maximum residue levels (MRLs) for iodine. Therefore iodine was included in Annex II of Council Regulation (EEC) 2377/90 (now repealed by Regulation (EC) No 470/2009) comprising the list of substances not subject to maximum residue limits. Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin lists iodine (including inorganic compounds) in Table 1 „Allowed substances" of the Annex with a „no MRL required" entry for all food producing species and all target tissues (including milk). Note eCA: This based on veterinary use of teat disinfection. Veterinary medicinal products with iodine as active substance can be

different from similar biocidal products with respect to application rate and duration.

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

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

Nevertheless, IRG has re-evaluated the residue studies submitted in its iodine inclusion dossier for PT3, a data package comprising eight published studies on iodine residues in milk after application of iodine-based teat-disinfection products. These residue studies are referenced in Doc. IIIA_06; Section A6.15/01-02 and A6.15/03-08 of the CAR.

In addition, a brief literature research with a focus on iodine concentrations in milk as a result of iodine-based teat-disinfection has been performed.

The respective study results (i.e. residue levels in milk) have been used for theoretical (linear) extrapolation to relevant uses of the IRG.

The results of the re-evaluated residue studies, the new studies as well as the dietary risk assessments (DRA) for IRG relevant exposure scenarios are summarized in the "*Discussion paper on iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group attached to section 13 of the IUCLID dossier.

The DRA demonstrated that – based on the extrapolated residue levels in milk – iodine exposure via milk is below the respective ULs for adults and children.

In the discussion paper it is finally proposed to discuss as soon as possible on BPC or Coordination Group level whether or not it is necessary to perform residue studies for iodine-based teat-disinfectants at the product authorization stage.

Note of the eCA – this is a reference to the original document included in the application. However, dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application.
The dietary risk assessment included below takes into account all agreements from these discussions.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure estimates are required for the risk assessment on animal health as well as for determining the worst-case human exposure estimate (WCCE). However, according to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small increases in serum iodine concentration have been found after teat dipping indicating

that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health.
This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in edible tissues/products is generally found to be highest in milk and not in meat. Meat was therefore not considered to be the major source of dietary iodine for the consumer.

As iodine is excreted in milk, and iodine-based teat disinfection does result in increased iodine levels in milk, a worst-case dietary exposure assessment from possible residues in milk is performed. The evaluation of exposure to iodine from milk is based on a study from O'-Brien (2013) on iodine measurements in milk (see "Monitoring Data") below.

Consumer Exposure

Calculation of WCCE: based on the O`Brien study (2013) on residues in milk of animals treated with iodine-based teat-disinfectants.
It is assumed that manual and automated application methods yield the same iodine residues in milk.
For details on the approach taken please see the supporting document "*Discussion paper: Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group.

Note of the eCA – this is a reference to the original document included in the application. However, dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account –
  1) pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
  2) post-milking teat-disinfection by manual dipping (based on 0.54% available iodine),
  3) post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)
  4) post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine), and
  5) pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable". Therefore, for the exposure calculations information of the O'Brien study is used, which considers 2x manual application. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).
  Although it is indicated in the intended use that three times milking per day is an option, this is considered an unusual situation, especially for larger herds. Two times milking a day is the standard for manual use (ESD for PT 3). Furthermore, as two times is the standard for manual milking, the additional contribution from three times milking a day in the bulk is considered low. Therefore, for the dietary risk assessment, two times milking a day is considered.

- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. As indicated above, 5 worst case scenarios are identified in the BPF of CVAS, with maximum available iodine concentrations of 0.14%, 0.34% and 0.54%. In the O'Brien study total iodine was measured in milk based on a tested formulation containing 0.5% iodine. The measured residues in milk are corrected using the available iodine content present in the worst case scenarios (WGIV 2017). Furthermore, as products can be used for pre- or post-application or pre-and post-application, these are included in the table below. Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded:
  Iodine exposure from all sources will be included in the assessment.
  The assessment will include exposure to iodine coming from:
  1. Teat treatment
  2. Teat treatment + background from milk (= total milk intake)
  3. Teat treatment + background from milk + dietary intake from other sources (= total dietary intake)
- Background in milk is variable due to differences in iodine concentrations in natural sources (drinking water and grass) and due to feed (supplemented with various amounts of iodine). The background was discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure WebEx meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx meeting it was noted that comparable values could be obtained from French and German monitoring studies.

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

which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (CVAS residues).

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

Comparison of estimated daily iodine intakes compared to upper limit of pre- or post-milking teat-disinfection by manual dipping/spraying

	Adults (0.45 L/day)	**Infants (0.46 L/day)**
	Estimated daily intake (µg/day) [% ofUL]	**Estimated daily intake (µg/day) [% ofUL]**
2x pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)		
Intake from milk due to teat treatment	27 5	28 14
Total milk intake*	117 20	120 60
Total dietary intake**	302 50	216 108
2x post-milking teat-disinfection by manual dipping (based on 0.54% available iodine)		
Intake from milk due to teat treatment	122 20	125 62
Total milk intake*	212 35	217 108
Total dietary intake**	397 66	313 156
2x post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)		
Intake from milk due to teat treatment	32 5	32 16
Total milk intake*	122 20	124 62
Total dietary intake**	307 51	220 110
2x post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine)		
Intake from milk due to teat treatment	77 13	79 39
Total milk intake*	167 28	171 85
Total dietary intake**	352 59	267 133
2x pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)		

Intake from milk due to teat treatment	59 10	60 30
Total milk intake*	149 25	152 76
Total dietary intake**	334 56	248 124

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

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

Conclusion: Pre- or post-milking teat-disinfection

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

1. pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
2. post-milking teat-disinfection by manual dipping (based on 0.54% available iodine),
3. post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)
4. post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine), and
5. pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)

pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 5% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 20% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 50% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 14% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 60% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 108% of the UL.

post-milking teat-disinfection by manual dipping (based on 0.54% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 20% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 35% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 66% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 62% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 108% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 156% of the UL.

post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 5% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 20% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 51% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 16% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 62% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 110% of the UL.

post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 13% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 28% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 59% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 39% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 85% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 133% of the UL.

pre- and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 10% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 25% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 56% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 30% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 76% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 124% of the UL.

Further information and considerations on scenarios [1, 2, 4 and 9]
Not relevant. All information has been provided or referenced in the respective chapters above.

Conclusion
Scenarios 1 (= Use # 1.1), 2 (= Use # 1.2), 4 (= Use # 1.4) and 9 (= Use # 1.9) described above are considered to be the worst-case scenarios of the intended use

"Use # 1 – Teat disinfection of milkable animals" and to cover all 9 scenarios (Use # 1.1 – 1.9) which are relevant for the teat disinfection products pertaining to meta SPCs 1-9 of the BPF.

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

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

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

Not required since iodine-based products of the BPF are not intended to be used by non-professionals.

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

Production/formulation of the biocidal product

The production of CVAS`s products is done in accordance with local and national occupational health and safety regulations.

The production of the products takes place in a semi-closed system. The raw materials are fed sequentially, using adequate dosing equipment, into a semi-closed stainless steel vessel equipped with a mixer and an air exhaust duct to prevent emission into the working environment. For working steps, where exposure of workers cannot be excluded, such as connecting lines, manual dosing of starting materials or quality control, the workers use adequate PPE (gloves, safety goggles completed by respiratory protection if required). The staff are trained workers.

From the vessels, the finished product is pumped to a filling station. The filling process is either done automatically under semi-closed conditions (product manufacturer: Calvatis) or done manually (product manufacturer: Schopf). As occupational health and safety regulations are observed (e.g. through regular measurements of air concentrations), exposure of industrial workers towards the finished product is minimal.

Environmental exposure

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

Disposal of the biocidal product:

Empty containers or liners that may retain some product residues are disposed of in a safe way. Small quantities of residual product are diluted with water and are flushed with water into the sewage treatment plant (STP). Empty containers are rinsed with plenty of water and disposed to normal or commercial waste. Significant quantities of waste product residues are not disposed of via the sewer if legally allowed but processed in a suitable STP or by a licensed waste disposal contractor.

Aggregated exposure

Aggregated exposure is not assessed, since a respective methodology is not available yet. Nevertheless, in the operator exposure assessment a total dietary intake is considered. For more details on the total dietary intake please refer to section "Estimating Livestock Exposure to Active Substances used in Biocidal Products" above.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1.1] / Mixing and loading of RTU (0.19% total iodine)	professionals	1/none	7.60E-04
		2/Gloves	7.60E-05
[1.1] / Mixing and loading of RTU (0.56% total iodine)	professionals	1/none	2.24E-03
		2/Gloves	2.24E-04
[1.1] / Mixing and loading of RTU (0.72% total iodine)	professionals	1/none	2.88E-03
		2/Gloves	2.88E-04
[1.1] / Mixing and loading of RTU (0.84% total iodine)	professionals	1/none	3.36E-03
		2/Gloves	3.36E-04
[1.2] / Mixing and loading of RTU (0.19% total iodine)	professionals	1/none	3.50E-06
		2/Gloves	3.50E-07
[1.2] / Mixing and loading of RTU (0.56% total iodine)	professionals	1/none	1.03E-05
		2/Gloves	1.03E-06
[1.2] / Mixing and loading of RTU (0.72% total iodine)	professionals	1/none	1.32E-05
		2/Gloves	1.32E-06
[1.2] / Mixing and loading of RTU (0.84% total iodine)	professionals	1/none	1.55E-05
		2/Gloves	1.55E-06
[2.1] / Application of teat disinfectant by manual	Exposure is considered covered by the mixing and loading scenario.		

dipping/foaming			
[2.2] / Application of teat disinfectant by automated dipping	No exposure of professionals occurs during automated dipping/foaming.		
[2.3] / Application of teat disinfectant by manual spraying - RTU (0.56% total iodine)	professionals	1/none	1.46E-02
		2/Gloves	4.63E-03
[2.3] / Application of teat disinfectant by manual spraying - RTU (0.72% total iodine)	professionals	1/none	1.87E-02
		2/Gloves, coverall and chemical resistant boots	2.52E-03
[2.4] / Application of teat disinfectant by automated spraying	No exposure of professionals occurs during automated spraying.		
[3.1] / Cleaning of teats by wiping with cloth (removal of freshly applied product) - RTU (0.19% total iodine)	professionals	1/none	1.10E-03
		2/ gloves	1.10E-04
[3.2] / Cleaning of teats by wiping with cloth (removal of dried product)	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.		
[3.3] / Cleaning of teats by robot	No exposure of professionals occurs during cleaning of teats by robot.		
[4.1] / Cleaning of equipment - RTU (0.19% total iodine)	professionals	1/none	1.75E-05
		2/ Gloves	1.75E-06
[4.1] / Cleaning of equipment - RTU (0.56% total iodine)	professionals	1/none	5.15E-05
		2/ Gloves	5.15E-06
[4.1] / Cleaning of equipment - RTU (0.72% total iodine)	professionals	1/none	6.62E-05
		2/ Gloves	6.62E-06
[4.1] / Cleaning of equipment - RTU (0.84% total	professionals	1/none	7.73E-05
		2/ Gloves	7.73E-06

iodine)			
[4.2] / Rinsing of automated dip/foam-system	No exposure of professionals occurs during rinsing of automated dipping/foaming-system.		
[4.3] / Rinsing of electronic sprayer	Exposure of professionals considered to be negligible during rinsing of electronic sprayer.		

1.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short\text{-}term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{medium\text{-}term}$	Not derived in the CAR and not relevant for HHRA.				
$AEL_{long\text{-}term}$ = Upper Intake Level (UL)	Human data				Adult: 600 µg/day (0.01 mg/kg bw/d) Toddler: 200 µg/day
ARfD	According to CAR, not applicable. Substance is not acute toxic or harmful.				
ADI	Not derived in the CAR and not relevant for HHRA. Instead of an ADI, a Recommended daily intake of 150-200 µg/day is given in the CAR.				
AEC = OEL (Occupational exposure limit)	Human data				0.1 ppm / 1 mg/m^3

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

Maximum residue limits or equivalent
Residue definitions

MRLs or other relevant reference values	Reference	Relevant commodities	Value
No MRL required" for all target tissues according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009.			

Risk for industrial users
Industrial exposure is not relevant.

Risk for professional users

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

Systemic effects

- As a worst-case, the estimated daily iodine intakes for meta-SPC 8 (0.54% available iodine) have been added to the individual tasks/scenarios.
- Intakes which exceed the UL are highlighted in red in the table below.

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Mixing and loading of RTU (0.19% total iodine) / [1.1]	1/ none	7.60E-04	8	28	43	74
	2/ Gloves	7.60E-05	1	21	36	67
Mixing and loading of RTU (0.56% total iodine) / [1.1]	1/ none	2.24E-03	22	42	57	88
	2/ Gloves	2.24E-04	2	22	37	68
Mixing and loading of RTU (0.72% total iodine) / [1.1]	1/ none	2.88E-03	29	49	64	95
	2/ Gloves	2.88E-04	3	23	38	69
Mixing and loading of RTU (0.84% total iodine) / [1.1]	1/ none	3.36E-03	34	54	69	100
	2/ Gloves	3.36E-04	3	23	38	69
Mixing and loading of RTU (0.19% total iodine) / [1.2]	1/ none	3.50E-06	0	20	35	66
	2/ Gloves	3.50E-07	0	20	35	66
Mixing and loading of RTU (0.56% total iodine) / [1.2]	1/ none	1.03E-05	0	20	35	66
	2/ Gloves	1.03E-06	0	20	35	66
Mixing and loading of RTU (0.72% total iodine) / [1.2]	1/ none	1.32E-05	0	20	35	66
	2/ Gloves	1.32E-06	0	20	35	66
Mixing and loading of RTU (0.84% total iodine) / [1.2]	1/ none	1.55E-05	0	20	35	66
	2/ Gloves	1.55E-06	0	20	35	66
Application of teat disinfectant by manual dipping/foaming / [2.1]	Exposure is considered covered by the mixing and loading scenario.					

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Application of teat disinfectant by automated dipping / [2.2]	No exposure of professionals occurs.					
Application of teat disinfectant by manual spraying – RTU (0.56% total iodine) / [2.3]	1/ none	1.46E-02	146	166	181	212
	2/ Gloves	4.63E-03	46	66	81	112
Application of teat disinfectant by manual spraying – RTU (0.72% total iodine) / [2.3]	1/ none	1.87E-02	187	207	222	253
	2/ Gloves, coverall and chemical resistant boots	2.52E-03	25	45	60	91
Application of teat disinfectant by automated spraying / [2.4]	No exposure of professionals occurs.					
Cleaning of teats by wiping with cloth (removal of freshly applied product) – RTU (0.19% total iodine) / [3.1]	1/ none	1.10E-03	11	31	46	77
	2/ gloves	1.10E-04	1	21	36	67
Cleaning of teats by wiping with cloth (removal of dried product) / [3.2]	Exposure of professionals considered to be negligible.					
Cleaning of teats by robot /	No exposure of professionals occurs.					

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
[3.3]						
Cleaning of equipment - RTU (0.19% total iodine) / [4.1]	1/ none	1.75E-05	0	20	35	66
	2/ Gloves	1.75E-06	0	20	35	66
Cleaning of equipment - RTU (0.56% total iodine) / [4.1]	1/ none	5.15E-05	1	21	36	67
	2/ Gloves	5.15E-06	0	20	35	66
Cleaning of equipment - RTU (0.72% total iodine) / [4.1]	1/ none	6.62E-05	1	21	36	67
	2/ Gloves	6.62E-06	0	20	35	66
Cleaning of equipment- RTU (0.84% total iodine) / [4.1]	1/ none	7.73E-05	1	21	36	67
	2/ Gloves	7.73E-06	0	20	35	66
Rinsing of automated dipping/foaming –system / [4.2]	No exposure of professionals occurs.					
Rinsing of electronic sprayer / [4.3]	Negligible exposure of professionals occurs.					

[1] as worst case, values derived from post-application use for the worst-case meta-SPC 8 are included.

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

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

Calculation sheet is included in annex 3.2.

Local effects

Local effects are only relevant for the application scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer".
The local exposure concentration is provided in the following table for the worst-case concentrations (0.72% total iodine).

Task/ Scenario	**Iodine in air inhaled (mg/m³)**	**% OEL (1 mg/m³)**	**Acceptable (yes/no)**
Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer – 0.56% total iodine / [2.3]	5.88E-02	5.9	yes
Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer – 0.72% total iodine / [2.3]	7.56E-02	7.6	yes

Combined scenarios

Explanatory note:

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

- Pre-milking disinfection using RTUs (0.19% total iodine)
    - Manual foaming using a foam cup (applies to meta-SPC 6.)

- Post-milking disinfection using RTUs (0.56%, 0.72% or 0.84% total iodine)
    - Manual dipping/foaming using a dip/foam cup (Dip applications apply to meta-SPCs 1-5 and 7 - 9. Foam applications apply to meta-SPCs 6, 7 and 9.)
    - Automated dipping/foaming (Dip applications apply to meta-SPCs 1-5 and 7 - 9. Foam applications apply to meta-SPCs 6, 7 and 9.)
    - Manual spraying using a trigger sprayer (applies to meta-SPCs 4, 5, 7 and 9)
    - Manual spraying using an electronic sprayer (applies to meta-SPCs 4, 5, 7 and 9)
    - Automated spraying by robot (applies to meta-SPCs 4, 5, 7 and 9)

- Pre- and post-milking disinfection using RTUs (0.19% total iodine)
    - Manual foaming using a foam cup (applies to meta-SPC 6.)

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

- RTU: 0.19% total iodine
- Residue values for the worst-case RTU product in meta-SPC 6 (0.14% available iodine) have been added to the estimated worker exposure.
- Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier / PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual foaming – RTU (0.19% total iodine)	1/ none	1.87E-03	19	24	39	69
	2/ gloves	1.87E-04	2	7	22	52

[1] Values derived from pre-application use for meta-SPC 6 (0.14% available iodine) are included.
[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013)
[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien), the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for toddler based on UK data (2008).

Calculation sheet is included in annex 3.2.

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

Assessment according to HEAdhoc Recommendation no. 13 (Jan. 2017), and taken into account iodine from other dietary sources (WG agreement WGIV 2017):
Tier 1: When using the RTU product (0.19% total iodine), **exposure from biocidal use** without considering PPE (Tier 1) results in 19% of the UL for manual foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 24% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 39% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 69% for manual foaming.

Tier 2: When using the RTU product (0.19% total iodine), **exposure from biocidal use** considering PPE (Tier 2) results in 2% of the UL for manual foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 7% for manual foaming.

Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier) results in 22% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 52% for manual foaming.

Conclusions pre-milking application:

For manual foam applications, no PPE is needed for safe use.

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

- RTU: 0.56%, 0.72% or 0.84% total iodine
- Residue values for the worst-case RTU product in meta-SPC 7 (0.14% available iodine), 8 (0.54% available iodine) or meta-SPC 9 (0.34% available iodine) have been added to the estimated worker exposure.
- Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier / PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual dipping/ foaming - RTU (0.84% total iodine)	1/ none	3.44E-03	34	54	69	100
	2/ gloves	3.44E-04	3	23	38	69
Automated dipping/foaming - RTU (0.84% total iodine)	1/ none	1.55E-05	0	20	35	66
Manual spraying using a trigger sprayer - RTU (0.56% total	1/ none	1.69E-02	169	174	189	220
	2/ Gloves	4,86E-03	49	54	69	100
Manual spraying using an electronic sprayer – RTU (0.56% total iodine)	1/ none	1.46E-02	146	151	166	197
	2/ Gloves	4.63E-03	46	51	66	97

Scenarios combined	Tier / PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Automated spraying by robot - RTU (0.56% total iodine)	1/ none	1.03E-05	0	5	20	51
Manual spraying using a trigger sprayer - RTU (0.72% total iodine)	1/ none	2.17E-02	217	230	245	276
	2/ Gloves, coverall and chemical resistant boots	2.82E-03	28	41	56	87
Manual spraying using an electronic sprayer – RTU (0.72% total iodine)	1/ none	1.88E-02	188	201	216	247
	2/ gloves, coverall and chemical resistant boots	2.52E-03	25	38	53	84
Automated spraying by robot - RTU (0.72% total iodine)	1/ none	1.32E-05	0	13	28	59

[1] Values derived from post-application use for meta-SPC 7 (0.14% available iodine), meta-SPC 8 (0.54% available iodine) or meta-SPC 9 (0.34% available iodine) are included.

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

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

Calculation sheet is included in annex 3.2.

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

Assessment according to HEAdhoc Recommendation no. 13 (Jan. 2017), and taken into account iodine from other dietary sources (WG agreement WGIV 2017)::

Tier 1: When using the RTU product (0.84% total iodine), **exposure from biocidal use,** without considering PPE (Tier 1) results in 34% of the UL for manual dipping/foaming and 0% of the UL for automated dipping/foaming.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 54% of the UL for manual dipping/foaming and 20% of the UL for automated dipping/foaming.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 69% of the UL for manual dipping/foaming and 35% of the UL for automated dipping/foaming.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 100% of the UL for manual dipping/foaming and 66% of the UL for automated dipping/foaming.

When using the RTU product (0.56% total iodine), **exposure from biocidal use,** without considering PPE (Tier 1) results in 169% of the UL for manual spraying using a trigger sprayer, 146% of the UL for manual spraying using an electronic sprayer and 0% of the UL for automated spraying.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 174% of the UL for manual spraying using a trigger sprayer, 151% of the UL for manual spraying using an electronic sprayer and 5% of the UL for automated spraying.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 189% of the UL for manual spraying using a trigger sprayer, 166% of the UL for manual spraying using an electronic sprayer and 20% of the UL for automated spraying.

Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 220% of the UL for manual spraying using a trigger sprayer, 197% of the UL for manual spraying using an electronic sprayer and 51% of the UL for automated spraying.

When using the RTU product (0.72% total iodine), **exposure from biocidal use,** without considering PPE (Tier 1) results in 217% of the UL for manual spraying using a trigger sprayer, 188% of the UL for manual spraying using an electronic sprayer and 0% of the UL for automated spraying.

Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 230% of the UL for manual spraying using a trigger sprayer, 201% of the UL for manual spraying using an electronic sprayer and 13% of the UL for automated spraying.

Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 245% of the UL for manual spraying using a trigger

sprayer, 216% of the UL for manual spraying using an electronic sprayer and 28% of the UL for automated spraying.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 276% of the UL for manual spraying using a trigger sprayer, 247% of the UL for manual spraying using an electronic sprayer and 59% of the UL for automated spraying.
Tier 2:

When using the RTU product (0.56% total iodine), **exposure from biocidal use,** considering PPE (Tier 2: gloves) results in 49% of the UL for manual spraying using a trigger sprayer and 46% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 54% of the UL for manual spraying using a trigger sprayer, and 51% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 69% of the UL for manual spraying using a trigger sprayer, and 66% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 100% of the UL for manual spraying using a trigger sprayer, and 97% of the UL for manual spraying using an electronic sprayer.

When using the RTU product (0.72% total iodine), **exposure from biocidal use,** considering PPE (Tier 2: gloves) results in 28% of the UL for manual spraying using a trigger sprayer and 25% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 41% of the UL for manual spraying using a trigger sprayer, and 38% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 56% of the UL for manual spraying using a trigger sprayer, and 53% of the UL for manual spraying using an electronic sprayer.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 87% of the UL for manual spraying using a trigger sprayer, and 84% of the UL for manual spraying using an electronic sprayer.
Furthermore, the OEL of 1 mg/m³ for iodine is not reached in the application scenario "Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer". The maximum value was 7.6% of the OEL when using RTUs containing 0.72% total iodine.
Conclusions post-milking application:

When using RTU product (0.84% total iodine):
For manual and automated dip/foam applications, no PPE is needed for safe use.

When using RTU product (0.56% total iodine):
For automated spraying, no PPE is needed for safe use.
For manual spraying application using a trigger sprayer or electronic sprayer chemical resistant gloves (90% protection) are needed for safe use.

When using RTU product (0.72% total iodine):
For automated spraying, no PPE is needed for safe use.

For manual spraying application using a trigger sprayer or electronic sprayer chemical resistant gloves (90% protection), coverall (90% protection) and chemical resistant boots are needed for safe use.

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

- RTU: 0.19% total iodine
- Residue values for the worst-case RTU product in meta-SPC 6 (0.14% available iodine) have been added to the estimated worker exposure.
- Intakes which exceed the UL are highlighted in red in the table below.

Scenarios combined	Tier / PPE	Estimated uptake mg/kg bw/d	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
Manual foaming - RTU (0.19% total iodine)	1/ none	1.87E-03	19	29	44	75
	2/ Gloves	1.87E-04	2	12	27	58

[1] Values derived from pre- and post-application use for meta-SPC 6 (0.14% available iodine) are included.

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

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

Calculation sheet is included in annex 3.2.

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

Assessment according to HEAdhoc Recommendation no. 13 (Jan. 2017)), and taken into account iodine from other dietary sources (WG agreement WGIV 2017):

Tier 1: When using the RTU product (0.19% total iodine),

exposure from biocidal use without considering PPE (Tier 1) results in 19% of the UL for manual foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, without considering PPE (Tier 1) results in 29% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption, without considering PPE (Tier 1) results in 44% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, without considering PPE (Tier 1) results in 75% for manual foaming.

Tier 2: When using the RTU product (0.19% total iodine), **exposure from biocidal use** considering PPE (Tier 2) results in 2% of the UL for manual foaming.
Exposure from biocidal use, including iodine from milk consumption due to teat treatment, considering PPE (Tier 2) results in 12% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption, considering PPE (Tier) results in 27% for manual foaming.
Exposure from biocidal use, including iodine from milk consumption and iodine from other dietary sources, considering PPE (Tier 2) results in 58% for manual foaming.

Conclusions pre- and post-milking application:

For manual foam applications, no PPE is needed for safe use.

Overall conclusion

In the following table, the conclusion of the acceptability of risk along with the relevant risk mitigation measures is summarized for each use per meta-SPC considering the whole concentration range. The outcome is based on calculations for the respective total iodine concentrations which, for readability reasons, are not presented in the sections above. Only worst-case concentrations have been presented as described under "general considerations" in section 2.2.6.2 above.

Meta-SPC	Total iodine concentration (relevant product)	Relevant use #	Acceptable risk (yes/no)	Risk mitigation measures
1	meta-SPC range: 0.19 – 0.24% Dip es barriere: 0.19%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
2	meta-SPC range: 0.25 – 0.40%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required

	Dip es Io-film: 0.40%	Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
3	meta-SPC range: 0.25 – 0.67% Dip es barriere S: 0.40% Dip es barriere RS: 0.67%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
4	meta-SPC range: 0.25 – 0.40% Dip es silver: 0.40%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.4 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	yes	Chemical resistant gloves
		Use # 1.5 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer	yes	Chemical resistant gloves
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
		Use # 1.8 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	yes	not required
5	meta-SPC range: 0.19 – 0.19% Dip es SF: 0.19%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.4 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	yes	not required

		Use # 1.5 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer	yes	not required
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
		Use # 1.8 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	yes	not required
6	meta-SPC range: 0.19 – 0.19% Dip es Io-foam: 0.19%	Use # 1.1 - Teat disinfection of milkable animals: Pre-milking teat disinfection by manual foaming	yes	not required
		Use # 1.3 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming	yes	not required
		Use # 1.7 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming	yes	not required
		Use # 1.9 - Teat disinfection of milkable animals: Pre- and post-milking teat disinfection by manual foaming	yes	not required
7	meta-SPC range: 0.29 – 0.56% calgodip D 1200: 0.29%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.3 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming	yes	not required
		Use # 1.4 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	yes	Chemical resistant gloves
		Use # 1.5 - Teat	yes	Chemical

		disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer		resistant gloves
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
		Use # 1.7 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming	yes	not required
		Use # 1.8 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	yes	not required
8	meta-SPC range: 0.29 – 0.84% calgodip D 3000 Film: 0.64% calgodip D 5000: 0.84%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
9	meta-SPC range: 0.57 – 0.72 calgodip D 3000: 0.72%	Use # 1.2 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	yes	not required
		Use # 1.3 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming	yes	not required
		Use # 1.4 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	yes	Chemical resistant gloves, coverall and chemical resistant boots
		Use # 1.5 - Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer	yes	Chemical resistant gloves, coverall and chemical resistant

				boots
		Use # 1.6 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated dipping	yes	not required
		Use # 1.7 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated foaming	yes	not required
		Use # 1.8 - Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	yes	not required

Risk for the general public

Exposure of the general public is not relevant.

Risk for consumers via residues in food

Calculation of WCCE: based on the O`Brien study (2013) on residues in milk of animals treated with iodine-based teat-disinfectants.
It is assumed that manual and automated application methods yield the same iodine residues in milk.
For details on the approach taken please see the supporting document "*Discussion paper: Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (29 June 2015) of the IRG PT3 sub-group.

Note of the eCA – this is a reference to the original document included in the application. However, dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account –
  1) pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
  2) post-milking teat-disinfection by manual dipping (based on 0.54% available iodine),
  3) post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)
  4) post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine), and
  5) pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual

milking and from three events per day for automatic milking are considered comparable". Therefore, for the exposure calculations information of the O'Brien study is used, which considers 2x manual application. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).

- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. As indicated above, 5 worst case scenarios are identified in the BPF of CVAS, with maximum available iodine concentrations of 0.14%, 0.34% and 0.54%. In the O'Brien study total iodine was measured in milk based on a tested formulation containing 0.5% iodine. The measured residues in milk are corrected using the available iodine content present in the worst case scenarios (WGIV 2017). Furthermore, as products can be used for pre- or post-application or pre-and post-application, these are included in the table below. Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded:
  Iodine exposure from all sources will be included in the assessment.
  The assessment will include exposure to iodine coming from:
  1. Teat treatment
  2. Teat treatment + background from milk (= total milk intake)
  3. Teat treatment + background from milk + dietary intake from other sources (= total dietary intake)
- Background in milk is variable due to differences in iodine concentrations in natural sources (drinking water and grass) and due to feed (supplemented with various amounts of iodine). The background was discussed in the Secure Webex meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study."
- Iodine dietary intake from other sources than milk was also discussed in the Secure WebEx meeting (3-10-2017), in which was concluded by eCAs from iodine based union authorisation applications: "The values from the UK survey were considered adequate to represent the EU iodine dietary intake from sources other than milk. Rounding of the values to 185 µg/day for adults and 96 µg/day for toddler was agreed." It should be noted that these values excluded iodine intake from milk. Furthermore, within this UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) 350 samples of dairy and seaweed products were purchased from eight areas of the UK. Levels of iodine found were generally in similar ranges to those reported from previous surveys (MAFF iodine in milk), Furthermore the reported values are in agreement with an EFSA scientific opinion on the use of iodine in feeding stuffs. It is noted that in the UK study report for the calculations for body weights 76 for adults and 14.5 kg for infants are considered, whereas 70 kg and 12 kg are used in the consumption calculations. Moreover, during the discussion at the Secure WebEx

meeting it was noted that comparable values could be obtained from French and German monitoring studies.

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (CVAS residues).

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

Comparison of estimated daily iodine intakes compared to upper limit of pre- or post-milking teat-disinfection by manual dipping/spraying

	Adults (0.45 L/day)	**Infants (0.46 L/day)**
	Estimated daily intake (µg/day) [% ofUL]	**Estimated daily intake (µg/day) [% ofUL]**
2x pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)		
Intake from milk due to teat treatment	27 5	28 14
Total milk intake*	117 20	120 60
Total dietary intake**	302 50	216 108
2x post-milking teat-disinfection by manual dipping (based on 0.54% available iodine)		
Intake from milk due to teat treatment	122 20	125 62
Total milk intake*	212 35	217 108
Total dietary intake**	397 66	313 156
2x post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)		
Intake from milk due to teat treatment	32 5	32 16
Total milk intake*	122 20	124 62
Total dietary intake**	307 51	220 110
2x post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine)		
Intake from milk due to teat treatment	77 13	79 39
Total milk intake*	167	171

	28	85
Total dietary intake**	352 59	267 133
2x pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)		
Intake from milk due to teat treatment	59 10	60 30
Total milk intake*	149 25	152 76
Total dietary intake**	334 56	248 124

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

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

Conclusion: Pre- or post-milking teat-disinfection

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

1. pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
2. post-milking teat-disinfection by manual dipping (based on 0.54% available iodine),
3. post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine), and
4. post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine), and
5. pre-and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)

pre-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 5% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 20% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 50% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 14% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 60% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 108% of the UL.

post-milking teat-disinfection by manual dipping (based on 0.54% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 20% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 35% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 66% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 62% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 108% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 156% of the UL.

post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 5% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 20% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 51% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 16% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 62% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 110% of the UL.

post-milking teat-disinfection by manual spraying using a trigger sprayer (based on 0.34% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 13% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 28% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 59% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 39% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 85% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 133% of the UL.

pre- and post-milking teat-disinfection by manual foaming (based on 0.14% available iodine)
For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 10% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 25% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 56% of the UL.

For infants, the estimated daily intake of iodine resulting from biocidal product use is maximally 30% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 76% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 124% of the UL.

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

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

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

Another notable example of exceedance of the UL was reported in an EFSA scientific opinion of the safety and efficacy of iodine compounds (2013). Please note that this report included the reference used for the background value for milk used in the residue calculations. In this paper it was stated that: 'The iodine content of food of animal origin, if produced from animals receiving the currently authorised maximum contents of total iodine in complete feed for dairy cows and laying hens (5 mg/kg), would represent a substantial risk to consumers, mainly for high-consuming (95th percentile) adults and toddlers. The risk would originate primarily from the consumption of milk and, to some extent, from consumption of eggs. The ULs would for adults be exceeded by a factor of 2 (1230 vs. 600 µg I/day), and for toddlers by a factor of 4 (840 vs. 200 µg I/day).' As a result of these exceedances the FEEDAP Panel recommended a reduction in the currently authorised maximum iodine contents in complete feed. The recommended reduced supplementation of 2 mg/kg would still result in an exceedance for the toddler (320 vs. 200 µg I/day).

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

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

1. Feed supplementation

2. Food and salt supplementation
3. Dietary supplements

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

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

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

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

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

assessment the additional milk intake due to teat disinfection is also taken into account separately.

3. The UL used is based on the limit values in the CAR were taken from/in line with the report of The Scientific Committee on Food (SCF). SCF based the iodine tolerable upper intake (UL) on studies in humans (male/female). The studies showed an increased serum thyroid-stimulating hormone (TSH) level in response to iodine intake and an enhanced response of TSH concentrations to thyrotropin-releasing hormone (TRH) at 1700-1800 µg/day. However, these changes were considered marginal and not associated with any clinical adverse effects. An uncertainty factor of 3 was selected to derive the UL for adults. For nutrients, an UF of 3 is a relatively high uncertainty factor, and therefore the derived UL is considered conservative. An additional factor of 3 was used to derive an UL for toddlers of 200 µg/day, which is standard approach to compensate differences between adults and children. Exceedance of the UL was discussed in various WG meetings. It was acknowledged that the value itself could be considered conservative, taken in mind that the value based on marginal effects and taken in mind that WHO derived a value of 1000 µg/day. However, no agreement was reached what would be considered acceptable for exceedance, and also there was no support to change the limit value at this stage. Therefore, the limit value should be considered during active substance renewal.

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

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

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

Not relevant, since neither additional active substances nor substances of concern are contained in the teat disinfection products within meta-SPCs 1-8 of the BPF.

1.2.7 Risk assessment for animal health

According to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small

increases in serum iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health. This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in edible tissues/products is generally found to be highest in milk and not in meat. In addition, iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products.

1.2.8 Risk assessment for the environment

1.2.8.1 Effects assessment on the environment

Information on PNEC values:

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 /L
Iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg /L
Iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg /L

Iodine: $PNEC(I_2)_{marine}$ = 0.059 µg /L
Iodate: $PNEC(IO_3^-)_{marine}$ = 5.85 µg /L
Iodide: $PNEC(I^-)_{marine}$ = 0.083 µg /L

Terrestrial compartment:

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

Information on background levels:

Background concentration of iodine in the environment (CAR, 2011 on iodine)	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L
Marine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 98 mg/kg_{dwt} (corresponding to 0.4 - 18 mg

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

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

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

Further Ecotoxicological studies

No data is available.

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

Not applicable since the risk assessment based on the available data indicates an acceptable use. However, environmental standards were exceeded for one or more compartments. Additional data at the renewal stage may be required.

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

Not needed since the risk assessment based on the available data indicates an acceptable use. However, environmental standards were exceeded for one or more compartments. Additional data at the renewal stage may be required.

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

Not relevant: the risk assessment indicates safe use and that target organism not at risk.

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

Such tests are only triggered in case when a habitat such as a water body, wetland, forest or field is treated. Any such treatment is not intended for the products.

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

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

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

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

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)

Data reported in the CAR is sufficient for the risk assessment.

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

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

Testing for distribution and dissipation in air (ADS)
Data reported in the CAR is sufficient.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)
No such spraying treatment is intended.

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 such spraying treatment is intended.

1.2.8.2 Exposure assessment

The NL-eCA requested in their "Results of 1st validation of UA CVAS iodine dossier" of 12/11/2015 that additional information on applied volumes per application should be provided. Therefore, the applicant performed two surveys among their customers and asked for measurements of the application rates of the products in the BPF (study reports attached to IUCLID section 13). Average consumption for nine products was determined by weighing dipping cups and spraying flacons before and after application. The number of replicas was three or eleven. Average consumption per cow per treatment ranged from 2.06-4.23 ml for dipping (n=7) and 3.94-4.53 ml for spraying (n=3). Foaming consumes 1.04 ml/treatment/cow (n=1).
For the calculation of the refined environmental risk assessment a worst-case application rate of 5 g (= 5 ml) per application was used (see below). Although the studies were not conducted according to any standard and were not according to GLP, the NL-eCA considers these studies as reliable.

General information

Assessed PT	PT 3
Assessed scenarios	Disinfection of teats of dairy cows
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, JRC Scientific and Technical Reports, Report nr. EUR 25116 EN, Publications Office of the European Union, Luxembourg, 2011
Approach	Average consumption The products can either be applied by • foaming (manual/automatic): pre- and/or post-milking (product volume of 5 ml/cow/milking) • dipping (manual/automatic): pre- and/or post-milking (product volume of 5 ml/cow/milking) or • spraying (manual/automatic): pre- and/or post-milking (product volume of 5 ml/cow/milking). Because the application rate is 5 ml/cow/milking for both foaming,

	dipping or spraying, emission was based on 5 mL/cow/milking.
Distribution in the environment	In agreement with the CAR (2013) on iodine.
Groundwater simulation	The calculation of the concentrations in groundwater was performed according to the approach described in the guidance Vol IV, part B where the concentration in pore water of agricultural soil is used as a first indication for groundwater concentrations.
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	In the following sections the use of the product *calgodip D 3000* (calculated for pre- plus post- teat disinfection by spraying) is represented for the BPR family.

Emission estimation

Formulation of the biocidal product
The formulation of the products is done in accordance with local and national occupational health and safety regulations.
The formulation of the products takes place in a semi-closed system. The raw materials are fed sequentially, using adequate dosing equipment, into a semi-closed stainless steel vessel equipped with a mixer. From the vessels, the finished product is pumped to a filling station. The filling process is either done automatically or manually.

Environmental exposure
If any spillages occur during the production, they are taken up with inert material (sand, earth, chemical absorbent, etc.) and are collected in dedicated drums properly labeled. They are disposed as chemical waste in accordance with local and national laws and regulations. Consequently, release to the environment is considered negligible.

Disposal of the biocidal product:
Empty containers or liners that may retain some product residues are disposed of in a safe way. Small quantities of residual product are diluted with water and are flushed with water into the sewage treatment plant (STP). Empty containers are rinsed with plenty of water and disposed to normal or commercial waste. Significant quantities of waste product residues are not disposed of via the sewer but processed in a suitable STP or by a licensed waste disposal contractor.

Disinfection of teats of dairy cows
Teat disinfections are applied by manual (using a dipping cup) or automated dipping, by manual (using a foam cup) or automated foaming, or by manual spraying (using a trigger sprayer or an electronic sprayer) or automated spraying by robot. Two environmental release pathways are possible: Releases into the environment through liquid manure (to soil) and via STP (into surface water and through application of sludge to soil).

As already mentioned in the table "General information" above, the same application rates (5 ml/cow/treatment) are used for spraying, dipping and foaming.

The maximum number of milking events per day is three. Even in the case of robotic milking, where individual cows may be milked as often as five times per day, the average milking frequency per herd is always below three milkings per day (experience from a test house specialised in veterinary farm research). Consequently, the ERA in this dossier also covers applications in installations equipped with robotic milking systems. The table below summarises the iodine concentrations and iodine consumption for each meta-SPC.

iodine concentrations and consumption				
MetaSPC	**iodine in product (g/L)[1]**	**daily applications**	**pre/post milking**	**daily iodine consumption (g/animal)[2]**
1	1.9-2.4	3	post	0.029-0.036
2	2.5-4.0		post	0.038-0.060
3	2.5-6.7		post	0.038-0.100
4	2.5-4.0		post	0.038-0.060
5	1.9		post	0.029
6	1.9		pre and/or post	0.057
7	2.9-5.6		post	0.044-0.084
8	2.9-8.4		post	0.044-0.126
9	5.7-7.2		post	0.086-0.108

[1] total iodine content in the formulation, including iodine from other constituents and impurities. No details could be provided for confidential reasons.
[2] based on 5 mL product per application per animal

The former meta-SPC #7 (now meta-SPC #9) represented by the product calgodip D 3000 results in the highest emission to the environment because of the total iodine contents in the product (7.2 g/L) and the number of daily applications (6). This would result in a daily iodine consumption of 0.216 g/animal (= 5 mL x 7.2 g/L x 6 applications/day). Therefore, predicted environmental concentrations (PECs) were calculated for former meta-SPC #7 (now meta-SPC #9) only representing the worst-case. It is therefore assumed that other products of the biocidal product family and their individual uses are covered by the results due to the use of calgodip D 3000. Emission to the STP, grassland, and arable land was calculated according to the ESD by applying the default parameters. The results are summarised in the table below. Meanwhile the BPF concept has been changed and pre- and post-application is only relevant for meta-SPC #6. Nevertheless, the following ERA calculations were not adapted and are still based on the daily iodine consumption of 0.216 g/animal. Since the actual maximum daily iodine consumptions in meta-SPC #1 to meta-SPC #9 (see table above) are all below this value, the present ERA calculations covers therefore all meta-SPCs.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	0.009 kg/d	Daily emission

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
$Soil_{grassland}$	0.572 kg	Amount of active substance in manure collected over 53 days
$Soil_{arable\ land}$	2.290 kg	Amount of active substance in manure collected over 212 days

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

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

The PEC's as calculated with the ESD represent the concentration after one manure application on arable land and one on grassland (Predicted Initial Environmental Concentrations, PIEC). However, agricultural soils are fertilised repeatedly and iodine may consequently accumulate in soils after successive years of manure applications. Therefore, the concentrations presented in the current assessment report are the concentrations after ten years, i.e. ten manure applications on arable land and forty on grassland. Concentrations in soils after ten years were calculated according to the addendum for PT18 (insecticide in stables), although the no-manure time was increased from 206 to 365 days.
Although iodine being an element does not degrade, it disappears from soils between two subsequent manure events due to leaching. The leaching rate constants and resulting PECs were calculated according to the guidance by applying an experimentally-

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

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

Fate and distribution in exposed environmental compartments

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

- Release via sewage treatment plant or
- Release into slurry/manure

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

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 (via STP)	yes	yes	yes	yes	yes	no	yes	yes	no
Scenario 1 (via slurry/ manure)	yes	yes	no	no	no	no	yes	yes	no

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

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	Source: ECHA[a], mol. weight for iodine (I_2)
Melting point	113.7	°C	Source: ECHA
Boiling point	184.5	°C	Source: ECHA

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Vapour pressure (at 25°C)	1×10^{-6}	Pa	Source: ECHA Although iodine (I_2) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised iodine species are volatile. Therefore, emission to air was not considered.
Water solubility (at 25°C)	100	g/L	Source: ECHA Value for the environmental relevant iodine species iodate and iodide. Solubility of iodine is 0.3 g/L.
Henry's law constant (12°)	4.05E-07	Pa m³/mol	Calculated
Log Octanol/water partition coefficient	-	Log 10	not relevant for inorganic substances
Organic carbon/water partition coefficient (Koc)	165.83	L/kg	not applied in the risk assessment. Overruled by K_d.
Solids-water partition coefficient in soil (K_d)	5.8	L/kg	Source: ECHA
Solids-water partition coefficient in sediment (Kp_{sed})	200	L/kg	Source: ECHA
Solids-water partition coefficient in suspended matter (Kp_{susp})	220	L/kg	Source: ECHA
Biodegradability	Not biode-gradable		Inorganic substance[b]

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

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

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

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
Air	negligible	Source: ECHA[a], based on laboratory

Water	80	and field experiments
Sludge	20	
Degraded in STP	0	

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

Calculated PEC values

In the following tables the PEC values for iodine and its transformation products iodide and iodate are provided for the use of *calgodip D 3000*, pre- plus post-milking treatment by spraying.

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	3.60	3.59E-01	1.74E-02	3.59E-02	1.74E-03	2.24E-02	4.27	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.10	5.34E-02	--	--	5.77E-02	11.0	--
arable land	--	0.302	1.47E-02	--	--	1.59E-02	3.03	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	3.31	1.61E-01	--	--	1.77E-01	33.2	--
arable land	--	2.02	9.80E-02	--	--	1.06E-01	20.2	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1 - via STP								
	4.98	4.96E-01	2.41E-02	4.96E-02	2.41 -03	3.09E-02	5.90	--
via slurry/manure – concentrations after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.52	7.38E-02	--	--	7.97E-02	15.2	--
arable	--	0.417	2.03E-02	--	--	2.19E-02	4.19	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea\ water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
land								
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	4.57	2.22E-01	--	--	2.44E-01	45.8	--
arable land	--	2.79	1.35E-01	--	--	1.47E-01	28.0	--

Primary and secondary poisoning

Primary and secondary poisoning

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

1.2.8.3 Risk characterisation

Atmosphere

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

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	0.001

The individual PEC/PNEC ratio for the STP scenario for iodine is below the trigger value of 1. For iodide and iodate, since no ecotoxicological reference values are available, no

PEC/PNEC-values were calculated. However, iodide and iodate are less toxic than iodine as shown for the aquatic compartment (see the PNEC-values for the aquatic environment below). Therefore, it is concluded that there is no unacceptable risk for the STP from the proposed use of the teat disinfectant products when residues are released to the sewer. However, dairy farms are not necessarily connected to the municipal sewer and domestic waste water may be purified on-site by individual sewage treatment plants. Considering that these systems are small (a few cubic meters), high loads of iodine may kill the microbial population therein instantly, resulting in malfunctioning of the plant. Therefore, a precautionary measure stating that residues must be discharged to the (liquid) manure depot or municipal sewer will be added to the SPC.

Aquatic compartment

The PEC and PNEC values for the sediment for the emission scenarios via STP are calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$ in line with the guidance Vol IV, part B. Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC values for the fresh water or seawater.

Summary table on calculated PEC/PNEC values for iodine				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
via STP				
	0.608	0.608	0.608	0.608
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**1.86**	**1.86**	n.r.	n.r.
arable land	0.512	0.512	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	**5.60**	**5.60**	n.r.	n.r.
arable land	**3.42**	**3.42**	n.r.	n.r.

n.r. (not relevant)

Summary table on calculated PEC/PNEC values for iodide				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
via STP				
	0.432	0.432	0.432	0.432
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	**1.32**	**1.32**	n.r.	n.r.
arable land	0.364	0.364	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer				

between two applications is considered.				
grassland	**3.98**	**3.98**	n.r.	n.r.
arable land	**2.43**	**2.43**	n.r.	n.r.

n.r. (not relevant)

Summary table on calculated PEC/PNEC values for iodate				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
via STP				
	0.008	0.008	0.008	0.008
via slurry/manure – PEC:PNEC ratios after four manure applications on grassland and one on arable land. Leaching from the top soil layer between two applications is considered.				
grassland	0.026	0.026	n.r.	n.r.
arable land	0.007	0.007	n.r.	n.r.
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.				
grassland	0.078	0.078	n.r.	n.r.
arable land	0.048	0.048	n.r.	n.r.

n.r. (not relevant)

Conclusion:
For the emission pathway via STP, the PEC/PNEC values for iodine, iodide and iodate in the aquatic compartment (surface water incl. sediment, marine water incl. sediment) are below the trigger value of 1 (max. 0.608). Therefore, unacceptable risk for the aquatic environment cannot expected.

Although iodate is the dominant iodine specie in soils under aerobic conditions, it may be transformed to iodide once entering the aquatic environment depending on the acidity and redox potential (oxygen concentrations). The maximum PEC/PNEC value for iodide is 3.98 after ten years of successive manure applications, while iodate results in a PEC:PNEC ratio of 0.078. Unacceptable risks may be expected in surface water low in oxygen. Iodine is however a natural occurring compound for which aquatic background levels are reported between 0.5 and 20 µg/L. Moreover, many uncertainties exist as currently available higher tier modelling (FOCUS PEARL, SWASH) are not suitable for inorganic substances such as iodine. It was therefore agreed that the natural background concentration replaces the PNEC as environmental standard. The accompanied risks are therefore considered acceptable.

Terrestrial compartment

Calculated PEC/PNEC values for iodine	
	PEC/PNEC$_{soil}$

via STP	**1.90**	
via slurry/manure		
	after one year	**after ten years**
grassland	**4.89**	**15.0**
arable land	**1.34**	**9.01**

Calculated PEC/PNEC values for iodide		
	$PEC/PNEC_{soil}$	
via STP	**5.20**	
via slurry/manure		
	after one year	**after ten years**
grassland	**13.4**	**41.1**
arable land	**3.69**	**24.7**

Calculated PEC/PNEC values for iodate		
	$PEC/PNEC_{soil}$	
via STP	0.102	
via slurry/manure		
	after one year	**after ten years**
grassland	0.262	0.803
arable land	0.072	0.484

Once released to soils, iodine will be transformed into iodide or iodate depending on the redox conditions. Iodine is therefore not relevant for the soil compartment. Unacceptable risks are expected for iodide in both arable and grassland after one year, i.e. after one or four manure applications respectively, while the PECs remain below the PNEC in case of iodate. The highest risks are expected for the most toxic specie iodide. These risks are nevertheless hypothetical as iodide only occurs in anaerobic i.e. flooded soils which may happen only incidentally. As the ecological impact of long-term flooding is more disastrous as the risks related to anthropogenic elevated iodine concentrations, the estimated PEC:PNEC ratios are considered unrealistic for agricultural soils for cattle and crops.

Iodine and iodine species occur naturally in the terrestrial environment for which natural global mean background concentration is 5 mg/kg dwt and varies with geographical locations and local geology. The background concentrations in sandy and clayey soils varies between 1.7-5.4 and 2.1-8.9 mg/kg dwt, respectively, while peaty soils may contain 18.7-98.2 mg/kg dwt. The expected PECs after ten years (0.177 mg iodine/kg wwt in grassland and 0.106 mg iodine/kg wwt in arable land) are in the lower range and therefore a significant increase of the background concentration cannot be expected. However, one should realise that the anthropogenic immission in soils due to teat

disinfection (42.3 g/ha/y)[2] is about two times higher than the natural atmospheric deposition (25.6 g/ha/y[3]), but the accompanied risks are nevertheless acceptable as the PEC:PNEC ratios for iodate remains below one. Unacceptable risks in soils are therefore not expected.

Groundwater

The concentration of iodine and iodide in the soil's pore water derived by equilibrium partitioning according to the Guidance is expected to be 33.2 µg /L in grassland and 20.2 µg/L in arable land (iodine and iodide) after repeated manure applications for ten successive years. The predicted iodate concentrations are 45.8 µg/L in grassland and 28.0 µg/L in arable land. Because similar concentrations could be expected in groundwater as well and the concentrations are above 0.1 µg/L, a higher tier exposure assessment is deemed necessary.

Note that the 0.1 µg/L limit is set for organic chemicals and therefore not feasible for iodine. Therefore, the predicted concentrations were compared to natural background concentrations. The PECs are expected to be within the natural background level of iodine in groundwater that ranges between 1 and 70 µg/L. Therefore, emission to groundwater is considered acceptable and no risk mitigation measures are necessary.

Primary and secondary poisoning

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

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

Teat disinfectants (scenario 1): Emission pathways

- via STP and/or
- via slurry/manure

Screening Step 2: Identification of relevant substances

[2] 2.2896 kg iodine is release to the manure intended for grassland or arable land (ESD outcome). Cows produce 7185 kg nitrogen annually (ESD default) which requires 42.3 ha agricultural land considering a nitrogen emission standards of 170 kg/ha for both arable land and grassland.

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

According to the "Transitional Guidance on mixture toxicity assessment for the environment (May 2014)" the following substances need to be considered as relevant for the mixture assessment:

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

Teat disinfectants (meta SPC 1-5):
The products contain only one active substance and substances of concern which are of environmental relevance are not present. In addition, no active substances from other PTs and no other ingredients that need consideration are contained. Thus, the number of relevant substances is 1, i.e. only active substance.

Screening Step 3: Screen on synergistic interactions

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

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

Aggregated exposure (combined for relevant emission sources)

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

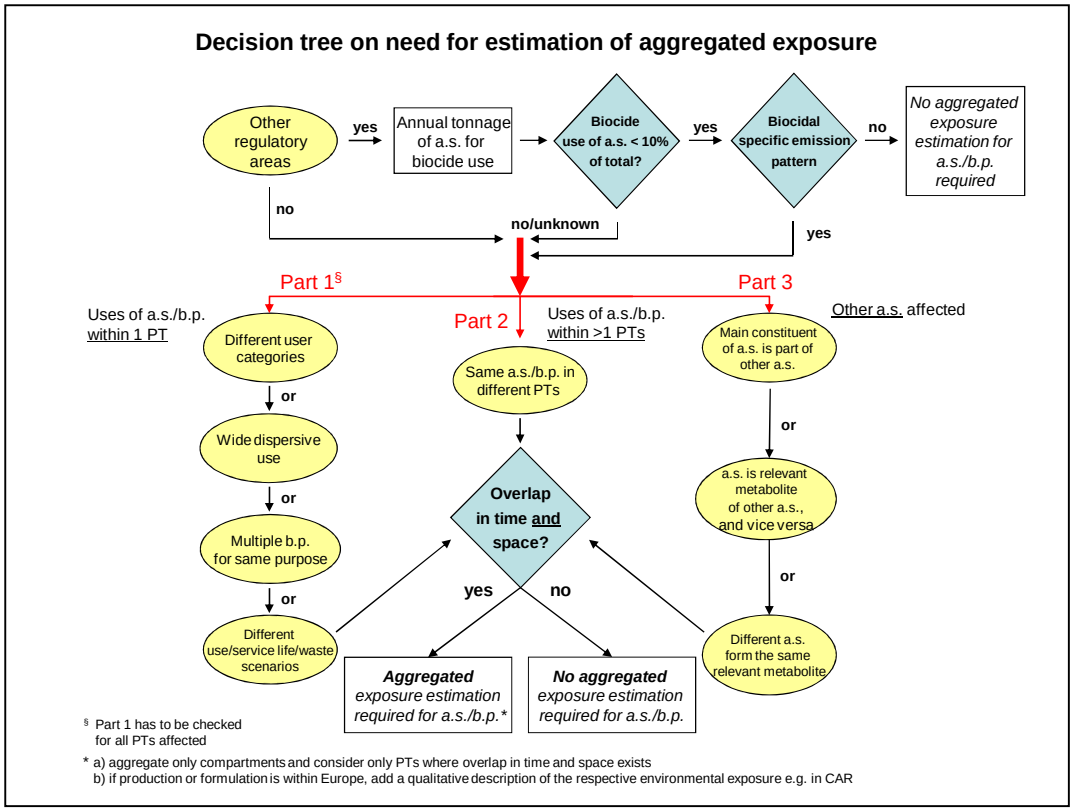


Figure 1: Decision tree on the need for estimation of aggregated exposure

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

1.2.9 Measures to protect man, animals and the environment

The following section is taken from the MSDS of the Dip es and calgodip products. Hence, it is redundant to the section on intended uses and the SPC.

Dip es products

Recommended methods and precautions concerning handling, use, storage, transport or fire

PRECAUTIONS FOR SAFE HANDLING
Advice on safe handling
Use product only as udder care product according to operating instruction.
Always read the label and product information before use.
Misuse may cause health damage.
Keep out of the reach of children.
Avoid release to the environment.
Instantly remove any clothing soiled by the product.

Fire preventions:
Product is not flammable.

EXPOSURE CONTROLS
Appropriate engineering controls:
Technical measures and the use of suitable working methods have priority before the application of personal protective equipment. Provide for good airing.
Suitable judgement methods of the examination of the effectiveness of the grieved preventive measures enclose measuring-technical and non-measuring-technical inquiry methods like they are described in the technical rules for danger materials (TRGS) 402.

Personal protective equipment:
The usual precautionary measures should be adhered to general rules for handling chemicals.
Avoid contact with the skin.
Take off immediately all contaminated clothing.
Wash hands during breaks and at the end of the work.
Do not eat, drink or smoke while working.

Respiratory protection:
not required

Breathing equipment:
not required

Hand protection:
Protective gloves recommended.
Chemical resistant protective gloves (EN 374).
Material of gloves: Chemical protection gloves of the category III in accordance with EN 374. Consider the data of the manufacturers at the permeability and break-through times as well as the special conditions on the job (mechanical load, contact duration)
Thickness: > 0.4 mm, Breakthrough time: > 480 min, Material: nitrile, butyl rubber
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
Penetration time of glove material: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:
Safety glasses recommendable.

STORAGE
Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels:
Store container in a well ventilated position.
Keep container tightly sealed.
Observe official regulations on storing of materials hazardous to water.
Keep away from foodstuffs, beverages and food.

SHELF-LIFE
18 months (see SPC for information on meta-SPC level)

TRANSPORT INFORMATION
Land transport ADR/RID and GGVS/GGVE (transborder/ inland):
No hazardous material

FIREFIGHTING MEASURES

Suitable extinguishing media
CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.

Unsuitable extinguishing media
Water with full jet

Special hazards arising from the substance or mixture
Formation of toxic gases is possible during heating or in case of fire: Carbon monoxide, Nitrogen oxides (NOx)

Advice for fire-fighters
Product is not flammable.

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment

DESCRIPTION OF FIRST AID MEASURES
General informations: No special measures required.

Following inhalation: Supply fresh air; consult doctor in case of symptoms.

Following skin contact: Instantly wash with water and soap and rinse thoroughly.

Following eye contact: Rinse opened eye for several minutes under running water (at least 15 minutes).

Following ingestion: Rinse out mouth and then drink plenty of water. Instantly call for doctor.

Most important symptoms and effects, both acute and delayed
No further relevant information available.

Indication of any immediate medical attention and special treatment needed:

Symptomatic treatment

Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

AIR
Significant release of Iodine from the biocidal product is considered to be negligible.

WATER, INCLUDING DRINKING WATER
Do not allow to enter drainage system, surface or ground water.

SOIL
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)

DISPOSAL CONSIDERATIONS
Waste treatment methods:
Hazardous waste (AVV). Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Must be specially treated under adherence to official regulations.

Uncleaned packaging:
Packagings cannot be reused. Contaminated packing must be completely emptied. Hand over to disposers of hazardous waste.

Recommended cleaning agent:
Water, if needed detergent.

Dip es products

calgodip D products

Recommended methods and precautions concerning handling, use, storage, transport or fire

PRECAUTIONS FOR SAFE HANDLING
Precautions for safe handling:
No special measures required.
Information about protection against explosions and fires:
No special measures required.

EXPOSURE CONTROLS / PERSONAL PROTECTIVE EQUIPMENT
General protective and hygienic measures:

The usual precautionary measures should be adhered to general rules for handling chemicals.
Avoid contact with the eyes.
Take off immediately all contaminated clothing
Keep away from foodstuffs, beverages and food.

Breathing equipment:
Not required.

Protection of hands:
Chemical resistant protective gloves (EN 374). The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Material of gloves:
Chemical protection gloves of the category III in accordance with EN 374. Consider the data of the manufacturers at the permeability and break-through times as well as the special conditions on the job (mechanical load, contact duration)
Thickness: > 0.4 mm, Breakthrough time: > 480 min, Material: nitrile, butyl rubber
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:
Tightly sealed safety glasses.

Body protection:
Wear suitable protective clothing.

STORAGE
Conditions for safe storage, including any incompatibilities
Requirements to be met by storerooms and containers:
No special requirements.

Information about storage in one common storage facility:
Special Storage of hazardous substances.

Further information about storage conditions:
Temperature of 40 °C to avoid
Protect from frost.

Storage class:
TRGS 510: LGK 12

SHELF-LIFE
24 months

TRANSPORT INFORMATION
UN-Number
ADR, ADN, IMDG, IATA: Void

UN proper shipping name
ADR, ADN, IMDG, IATA: Void

Transport hazard class(es)
ADR, ADN, IMDG, IATA: Class: Void

Packing group
ADR, IMDG, IATA Void

Environmental hazards
Not applicable.

Transport in bulk according to Annex II of Marpol and the IBC Code
Not applicable.

UN "Model Regulation": -

FIREFIGHTING MEASURES

Suitable extinguishing media:
CO2, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.
Use fire fighting measures that suit the environment.

Special hazards arising from the substance or mixture
No further relevant information available.

Advice for fire-fighters
Protective equipment: Wear self-contained breathing apparatus.
Additional information Product is not combustible.

Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available; emergency measures to protect the environment

DESCRIPTION OF FIRST AID MEASURES
After inhalation
Supply fresh air; consult doctor in case of symptoms.

After skin contact
Wash with water and soap. If skin irritation continues, consult a doctor.

After eye contact
Rinse opened eye for several minutes under running water. Then consult doctor.

After swallowing
Rinse out mouth and then drink plenty of water. Seek medical advice.

Most important symptoms and effects, both acute and delayed
No further relevant information available.

Indication of any immediate medical attention and special treatment needed
No further relevant information available.

Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil

AIR
Significant release of Iodine from the biocidal product is considered to be negligible.

WATER, INCLUDING DRINKING WATER
Do not allow product to reach sewage systems or water bodies in great quantities.

SOIL
Absorb with liquid-binding material (sand, diatomite, universal binder). Do not use combustible material like sawdust. Dispose of the material collected according to regulations.

Procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non-professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)

DISPOSAL CONSIDERATIONS
Waste treatment methods
Recommendation Must be specially treated with regard to official regulations.

Waste disposal key number
Corresponding to the regulation of the European Waste catalogue the relation of the waste key numbers has to be made specific to industry and process.

European waste catalogue
Corresponding to the regulation of the EWC the relation of the waste key numbers has to be made specific to industry and process.

Uncleaned packagings
Contaminated packages must be completely emptied and may be reused after proper cleaning.

Recommendation
Disposal must be made according to official regulations.

1.2.10Assessment of a combination of biocidal products

Not relevant. The biocidal products are not intended to be authorised for the use with other biocidal products.

1.2.11 Comparative assessment

Not relevant.

2. ANNEXES

2.1. List of studies for the biocidal product family

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
						Yes	No
B3.1 B3.2 B3.3 B3.4.1.1 B3.5.12 B3.8 B3.9	Mo5242	Manka, S.	2015	Determination of Physico-Chemical Properties and Storage Stability Test for Dip es SF	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.5.12 B3.8 B3.9	Mo5242	Manka, S.	2015	Determination of Physico-Chemical Properties and Storage Stability Test for Dip es Io-foam	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.8 B3.9	Mo5242	Manka, S.	2015	Determination of Physico-Chemical Properties and Storage Stability Test for Dip es barriere	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B3.1 B3.2 B3.3 B3.4.1.1 B3.9	15031610N978	Affolter, O.	2015	Determination of the accelerated storage of calgodip D 3000-Film	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.5.12 B3.8 B3.9	15031611N978	Affolter, O.	2015	Determination of the accelerated storage of calgodip D 3000	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.9	15031612N978	Affolter, O.	2015	Determination of the accelerated storage of calgodip D 5000	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.5.12 B3.8 B3.9	15031613N978	Affolter, O.	2015	Determination of the accelerated storage of calgodip D 1200	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.8 B3.9	15031703N978	Affolter, O.	2015	Determination of the accelerated storage of Dip es lo-film	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B3.1 B3.2 B3.3 B3.4.1.1 B3.8 B3.9	15031706N978	Affolter, O.	2015	Determination of the accelerated storage of Dip es barriere RS	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.8 B3.9	15031708N978	Affolter, O.	2015	Determination of the accelerated storage of Dip es barriere S	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.1 B3.5.12 B3.8 B3.9	Mo5242	Manka, S.	2015	Determination of Physico-Chemical Properties and Storage Stability Test for Dip es silver	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.2 B3.5.12 B3.8 B3.9	Mo5346	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for Dip es silver	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B3.1 B3.2 B3.3 B3.4.1.2 B3.5.12 B3.8 B3.9	Mo5347	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for Dip es lo-foam	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.2 B3.8 B3.9	Mo5349	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for Dip es barriere	CVAS Development GmbH		NO
B3.1 B3.2 B3.3 B3.4.1.2 B3.8 B3.9	Mo5350	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for Dip es lo-film	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5345	Manka, S.	2016	CoA: Mo5345 Calgodip D 3000, 12 month	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5345	Manka, S.	2016	CoA: Mo5345 Calgodip D 3000, 3 month	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5345	Manka, S.	2016	CoA: Mo5345 Calgodip D 3000, 6 month	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5345	Manka, S.	2015	CoA: Mo5345 Calgodip D 3000, Start	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5348	Manka, S.	2016	CoA: Mo5348 Calgodip D 3000 Film, 12 month	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B3.2 B3.4.1.2	Mo5348	Manka, S.	2016	CoA: Mo5348 Calgodip D 3000 Film, 3 month	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5348	Manka, S.	2016	CoA: Mo5348 Calgodip D 3000 Film, 6 month	CVAS Development GmbH		NO
B3.2 B3.4.1.2	Mo5348	Manka, S.	2015	CoA: Mo5348 Calgodip D 3000 Film, Start	CVAS Development GmbH		NO
B3.4.1.2	Mo5345	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for calgodip D 3000	CVAS Development GmbH		NO
B3.4.1.2	Mo5348	Manka, S.	2017	Determination of Phvsico-Chemical Properties and Storage Stability Test for calgodip D 3000 Film	CVAS Development GmbH		NO
B4.16	BE01-01-2018	Eschbach, B.	2018	Determination of the behaviour of Calgodip D 5000 with regard to the corrosion of metals	CVAS Development GmbH		NO
B4.16	BE01-02-2018	Eschbach, B.	2018	Determination of the behaviour of DIP es silver with regard to the corrosion of metals	CVAS Development GmbH		NO
B5.1	15031701N926	Affolter, O.	2015	Validation of an Analytical Method for the determination of Iodine in the several samples containing Iodine	CVAS Development GmbH	YES	
B6.7	16.8.1.0194/Rev 1	Gerhardts, A.	2016	Prüfbericht Nr. / Test report no. 16.8.1.0194/Rev1: Dip es SF, modified EN16437	CVAS Development GmbH		NO
B6.7	16.8.1.0195/Rev 2	Gerhardts, A.	2016	Prüfbericht Nr./Test report no. 16.8.1.0195/Rev2: Calgodip D1200, modified EN16437	CVAS Development GmbH		NO
B6.7	306.17-1	Bartuli, J.	2017	FINAL REPORT: Dip es silver, EN1656, after storage	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	306.17-1	Bartuli, J.	2017	FINAL REPORT: Dip es silver, EN1657, after storage	CVAS Development GmbH		NO
B6.7	306.17-2	Bartuli, J.	2017	FINAL REPORT: Dip es barriere EN1656, after storage	CVAS Development GmbH		NO
B6.7	306.17-2	Bartuli, J.	2017	FINAL REPORT: Dip es barriere EN1657, after storage	CVAS Development GmbH		NO
B6.7	306.17-3	Bartuli, J.	2017	FINAL REPORT: Dip es Io-film, EN1656, after storage	CVAS Development GmbH		NO
B6.7	306.17-3	Bartuli, J.	2017	FINAL REPORT: Dip es Io-film, EN1657, after storage	CVAS Development GmbH		NO
B6.7	306.17-4	Bartuli, J.	2017	FINAL REPORT: Dip es Io-foam, EN1656, after storage	CVAS Development GmbH		NO
B6.7	306.17-4	Bartuli, J.	2017	FINAL REPORT: Dip es Io-foam, EN1657, after storage	CVAS Development GmbH		NO
B6.7	4478-1	Teulier, M.	2017	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN synthetic skin) according to a protocol adapted from the NF EN 16437 standard in drop/dip	CVAS Development GmbH		NO
B6.7	4479-1	Teulier, M.	2017	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN synthetic skin) according to a protocol adapted from the NF EN 16437 standard in drop/dip	CVAS Development GmbH		NO
B6.7	D10-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D10-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	D10-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D10-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000	CVAS Development GmbH		NO
B6.7	D10-4/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D10-4/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000	CVAS Development GmbH		NO
B6.7	D104/2016	Slitrova, J.; Kremlova, E.	2016	Test report No. D104/2016 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC:2007) ACTIVITY OF THE PRODUCT DIP ES SF	CVAS Development GmbH		NO
B6.7	D10-5/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D10-5/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000	CVAS Development GmbH		NO
B6.7	D105-1/2016	Slitrova, J.; Kremlova, E.	2016	Test report No. D105/2016 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC:2007) ACTIVITY OF THE PRODUCT CALGODIP D 1200	CVAS Development GmbH		NO
B6.7	D11-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D11-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000 FILM	CVAS Development GmbH		NO
B6.7	D11-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D11-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 3000 FILM	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	D12-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D12-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 1200	CVAS Development GmbH		NO
B6.7	D12-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D12-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 1200	CVAS Development GmbH		NO
B6.7	D12-4/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D12-4/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 1200	CVAS Development GmbH		NO
B6.7	D12-5/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D12-5/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 1200	CVAS Development GmbH		NO
B6.7	D125-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D125-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE S	CVAS Development GmbH		NO
B6.7	D125-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D125-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE S	CVAS Development GmbH		NO
B6.7	D13-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D13-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT CALGODIP D 5000	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	D13-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D13-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT CALGODIP D 5000	CVAS Development GmbH		NO
B6.7	D4-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D4-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE	CVAS Development GmbH		NO
B6.7	D4-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D4-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE	CVAS Development GmbH		NO
B6.7	D5-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D5-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES SILVER	CVAS Development GmbH		NO
B6.7	D5-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D5-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES SILVER	CVAS Development GmbH		NO
B6.7	D5-4/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D5-4/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES SILVER	CVAS Development GmbH		NO
B6.7	D5-5/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D5-5/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES SILVER	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	D6-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D6-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FILM	CVAS Development GmbH		NO
B6.7	D6-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D6-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FILM	CVAS Development GmbH		NO
B6.7	D7-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D7-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FOAM	CVAS Development GmbH		NO
B6.7	D7-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D7-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FOAM	CVAS Development GmbH		NO
B6.7	D7-4/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D7-4/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FOAM	CVAS Development GmbH		NO
B6.7	D7-5/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D7-5/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES IO-FOAM	CVAS Development GmbH		NO
B6.7	D8-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D8-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE RS	CVAS Development GmbH		NO

BPR datapoint **Annex III** B = product level	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
B6.7	D8-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D8-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES BARRIERE RS	CVAS Development GmbH		NO
B6.7	D9-1/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D9-1/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES SF	CVAS Development GmbH		NO
B6.7	D9-2/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D9-2/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES SF	CVAS Development GmbH		NO
B6.7	D9-4/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D9-4/2015 - DETERMINATION OF BACTERICIDAL (EN 1656:2009/AC) ACTIVITY OF THE PRODUCT DIP ES SF	CVAS Development GmbH		NO
B6.7	D9-5/2015	Slitrova, J.; Kremlova, E.	2015	Test report No. D9-5/2015 - DETERMINATION OF YEASTICIDAL (EN 1657:2005/AC) ACTIVITY OF THE PRODUCT DIP ES SF	CVAS Development GmbH		NO
B7.10.1.	BC124-00002	SCC gmbH	2015	Discussion paper – Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety	IRG PT3 sub-group	YES	

2.2. Output tables from exposure assessment tools

Human health risk assessment

Justification regarding inhalation exposure towards vapour
Background

Inhalation exposure towards vapours of iodine was a point of discussion at TOX WG-IV-2017 for two Union Authorisation dossiers (eCA NL). The issue was further discussed in an *ad hoc* follow-up meeting (secure WebEx discussion on 25 October 2017). In preparation of the discussion, one applicant submitted a detailed justification as to why inhalation exposure towards iodine vapour is negligible for biocidal products based on either iodophor type 1 (iodine complexed with surfactants) or iodophor type 2 (PVP-iodine).

The TOX working group followed the argumentation of the applicant and the issue was closed. As eCA NL and UK considered the argumentation relevant for all iodine dossiers, it was proposed to share the argumentation within the IRG PT3 sub-group.

The argumentation discussed and agreed in the *ad hoc* follow-up meeting of October 2017 is provided in the following. It may be used by applicants who are members of the IRG PT3 sub-group to support their conclusions regarding negligible vapours of iodine in the human health exposure and risk assessments.

Considerations regarding evaporation of iodine from iodine-based biocidal products

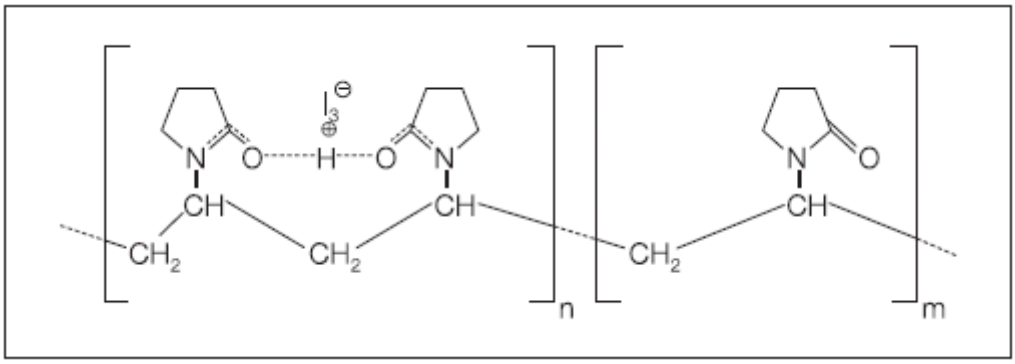
In the iodine Assessment Report for PTs, 1, 3, 4 and 22 (Sweden 2013) it is clearly detailed in the identity chapter 2.1.1, that "In the case of iodophor 1 (iodine complexed with surfactants) […] iodine can be regarded as the active substance […] present in stabilized (complexed) form." Analogously, iodophor 2 (PVP-iodine) is described as a complex between iodine and PVP. In summary, both iodophors are regarded as carriers which are capable of complexing iodine in their scaffolds.

As the iodine dossier has been approved by all EU member states, it can be concluded that there is a common understanding about the fact that iodine used in PT 3 is complex-bound either to surfactants (in the case of iodophor 1) or PVP (in the case of PVP-iodine, i.e. iodophor 2).

Despite the clear description in the iodine dossier, more details on the structure of iodophors and the release of complex-bound iodine from these iodophors are included below.

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

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



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

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

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

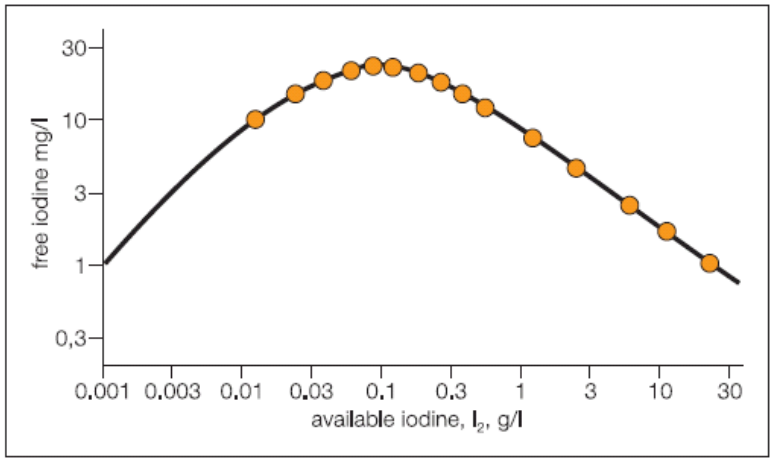
Iodide (I^-) = *reaction partner of available iodine in the iodophor*

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

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

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

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


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

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

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

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

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

Conclusion

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

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

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

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

References

Ref [1]

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

TDS_BASF_PVP-Iodine-grades.pdf

Ref [2]

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

20.3.2.1 Iodophors

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

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

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

Scenario [1.1] - Mixing and loading of RTU product for dip/foam cup or trigger sprayer

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

Dermal exposure: Mixing/Loading model 4 - Professional pouring liquid (TNsG, 2002); model covers all relevant M/L tasks performed on a 8-h working day
Inhalation exposure: not relevant
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,19	0,19
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	ml/treatment	0,20	0,20
Duration	min	n.r.	n.r.
Potential hand deposit [product]	mg	200,0	200,0
penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	200,0	20,0
Total dermal exposure			
Total dermal deposit [a.s.]	mg	0,380	0,038
Penetration through skin [a.s.]	mg	0,046	0,005
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**7,60E-04**	**7,60E-05**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**7,60**	**0,76**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**7,60E-04**	**7,60E-05**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**7,60**	**0,76**

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

Dermal exposure: Mixing/Loading model 4 - Professional pouring liquid (TNsG, 2002); model covers all relevant M/L tasks performed on a 8-h working day
Inhalation exposure: not relevant
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,56	0,56
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	ml/treatment	0,20	0,20
Duration	min	n.r.	n.r.
Potential hand deposit [product]	mg	200,0	200,0
penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	200,0	20,0
Total dermal exposure			
Total dermal deposit [a.s.]	mg	1,120	0,112
Penetration through skin [a.s.]	mg	0,134	0,013
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**2,24E-03**	**2,24E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**22,40**	**2,24**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**2,24E-03**	**2,24E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**22,40**	**2,24**

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

Dermal exposure: Mixing/Loading model 4 - Professional pouring liquid (TNsG, 2002); model covers all relevant M/L tasks performed on a 8-h working day
Inhalation exposure: not relevant
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,72	0,72
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	ml/treatment	0,20	0,20
Duration	min	n.r.	n.r.
Potential hand deposit [product]	mg	200,0	200,0
penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	200,0	20,0
Total dermal exposure			
Total dermal deposit [a.s.]	mg	1,440	0,144
Penetration through skin [a.s.]	mg	0,173	0,017
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**2,88E-03**	**2,88E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**28,80**	**2,88**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**2,88E-03**	**2,88E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**28,80**	**2,88**

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

Dermal exposure: Mixing/Loading model 4 - Professional pouring liquid (TNsG, 2002); model covers all relevant M/L tasks performed on a 8-h working day
Inhalation exposure: not relevant
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,84	0,84
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	ml/treatment	0,20	0,20
Duration	min	n.r.	n.r.
Potential hand deposit [product]	mg	200,0	200,0
penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	200,0	20,0
Total dermal exposure			
Total dermal deposit [a.s.]	mg	1,680	0,168
Penetration through skin [a.s.]	mg	0,202	0,020
Number of applications/day	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**3,36E-03**	**3,36E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**33,60**	**3,36**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**3,36E-03**	**3,36E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**33,60**	**3,36**

Scenario [1.2] - Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device

Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device - 1x/day (for post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,19	0,19
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	1	1
Potential hand deposit	mg	0,92	0,92
penetration through gloves	%	100	10
Actual dermal deposit	mg	0,9	0,1
Total dermal exposure			
Total dermal deposit [a.s.]	mg	1,75E-03	1,75E-04
Penetration through skin *[a.s.]*	mg	2,10E-04	2,10E-05
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**3,50E-06**	**3,50E-07**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,03**	**0,00**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**3,50E-06**	**3,50E-07**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,03**	**0,00**

Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device - 1x/day (for post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,56	0,56
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	1	1
Potential hand deposit	mg	0,92	0,92
penetration through gloves	%	100	10
Actual dermal deposit	mg	0,9	0,1
Total dermal exposure			
Total dermal deposit [a.s.]	mg	5,15E-03	5,15E-04
Penetration through skin *[a.s.]*	mg	6,18E-04	6,18E-05
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**1,03E-05**	**1,03E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,10**	**0,01**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**1,03E-05**	**1,03E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,10**	**0,01**

Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device - 1x/day (for post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,72	0,72
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	1	1
Potential hand deposit	mg	0,92	0,92
penetration through gloves	%	100	10
Actual dermal deposit	mg	0,9	0,1
Total dermal exposure			
Total dermal deposit [a.s.]	mg	6,62E-03	6,62E-04
Penetration through skin *[a.s.]*	mg	7,95E-04	7,95E-05
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**1,32E-05**	**1,32E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,13**	**0,01**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**1,32E-05**	**1,32E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,13**	**0,01**

Mixing and loading for electronic sprayer, automated dipping/foaming-system or robotic milking device - 1x/day (for post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,84	0,84
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	1	1
Potential hand deposit	mg	0,92	0,92
penetration through gloves	%	100	10
Actual dermal deposit	mg	0,9	0,1
Total dermal exposure			
Total dermal deposit [a.s.]	mg	7,73E-03	7,73E-04
Penetration through skin *[a.s.]*	mg	9,27E-04	9,27E-05
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**1,55E-05**	**1,55E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,15**	**0,02**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**1,55E-05**	**1,55E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,15**	**0,02**

Scenario [2.3] - Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer

Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer - 2x/day (post-milking)

Dermal and inhalation (aerosol) exposure: Consumer spraying and dusting model 2, 2. Hand-held trigger spray
According to HEAdhoc Recommendation no. 13 (Jan. 2017)
Assumtions acc. to Biocides Human Health Exposure Methodology, 2015: 82 cows, 10 sec/cow

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,56	0,56
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hand/forearms)	mg/min	36,1	36,1
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit	mg	493	493
Penetration through gloves	%	100	10
Actual dermal deposit	mg	493	49,3
Indicative value (legs, feet, face)	mg/min	9,7	9,7
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit	mg	132,57	132,57
Clothing penetration	%	100	100
Actual dermal deposit	mg	132,57	132,57
Total dermal exposure			
Total dermal deposit [a.s.]	mg	3,505	1,019
Penetration through skin [a.s.]	mg	0,421	0,122
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**1,40E-02**	**4,07E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**140,21**	**40,75**
Exposure by inhalation [aerosol]			
Indicative value	mg/m³	10,5	10,5
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0,285	0,285
Inhaled product	mg	2,990	2,990
Inhalted a.s.	mg	0,017	0,017
Number of applications	counts	2	2
Systemic exposure via inhalation route	**mg/kg bw/day**	**5,58E-04**	**5,58E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**5,58**	**5,58**
Active substance, inhaled per m³	**mg/m³**	**5,88E-02**	**5,88E-02**
OEL	**mg/m³**	**1,00**	**1,00**
% OEL	**%**	**5,88**	**5,88**
Total systemic exposure	**mg/kg bw/day**	**1,46E-02**	**4,63E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**145,79**	**46,33**

Application of teat disinfectant by spraying using a trigger sprayer or electronic sprayer - 2x/day (post-milking)

Dermal and inhalation (aerosol) exposure: Consumer spraying and dusting model 2, 2. Hand-held trigger spray

According to HEAdhoc Recommendation no. 13 (Jan. 2017)

Assumtions acc. to Biocides Human Health Exposure Methodology, 2015: 82 cows, 10 sec/cow

		Tier 1	Tier 2 gloves, coverall
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,72	0,72
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hand/forearms)	mg/min	36,1	36,1
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit	mg	493	493
Penetration through gloves	%	100	10
Actual dermal deposit	mg	493	49,3
Indicative value (legs, feet, face)	mg/min	9,7	9,7
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Potential dermal deposit	mg	132,57	132,57
Clothing penetration	%	100	10
Actual dermal deposit	mg	132,57	13,26
Total dermal exposure			
Total dermal deposit [a.s.]	mg	4,507	0,451
Penetration through skin [a.s.]	mg	0,541	0,054
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**1,80E-02**	**1,80E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**180,27**	**18,03**
Exposure by inhalation [aerosol]			
Indicative value	mg/m³	10,5	10,5
Duration	sec/cow	10	10
Number of cows	counts	82	82
Total duration	min	13,7	13,7
Inhalation rate	m³/min	0,021	0,021
Inhaled volume	m³	0,285	0,285
Inhaled product	mg	2,990	2,990
Inhalted a.s.	mg	0,022	0,022
Number of applications	counts	2	2
Systemic exposure via inhalation route	**mg/kg bw/day**	**7,18E-04**	**7,18E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level		**7,18**	**7,18**
Active substance, inhaled per m³	**mg/m³**	**7,56E-02**	**7,56E-02**
OEL	**mg/m³**	**1,00**	**1,00**
% OEL	**%**	**7,56**	**7,56**
Total systemic exposure	**mg/kg bw/day**	**1,87E-02**	**2,52E-03**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**187,44**	**25,20**

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

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

Dermal exposure: generic approach, worst-case estimate: 0.1% of the amount on the surface area contacts the palm of the hands; Application of the layer thickness (44 cm^2/teat x 4 teats x 0.01 cm = 1.76 cm^3/cow = 1.76 mL/cow),
Inhalation exposure: not relevant
According to HEAdhoc Recommendation no. 13 (Jan. 2017)
Assumption acc. to Biocides Human Health Exposure Methodology, 2015: 82 cows

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,19	0,19
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Product amount (film thickness approach)	ml/cow	1,76	1,76
Number of cows	counts	82	82
Product amount	ml	144,32	144,32
Product amount	mg	144320	144320
Product amount with contact to hand (0.1%)	mg	144,32	144,32
Penetration through gloves	%	100	10
Actual dermal deposit [product]	mg	144,32	14,43
Total dermal exposure			
Total dermal deposit [a.s.]	mg	0,274	0,027
Penetration through skin [a.s.]	mg	0,033	0,003
Number of applications	counts	2	2
Systemic exposure via dermal route	**mg/kg bw/day**	**1,10E-03**	**1,10E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**10,97**	**1,10**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**1,10E-03**	**1,10E-04**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**10,97**	**1,10**

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

Cleaning of equipment such as dip/foam cups, trigger sprayer after use - 1x/day (pre- and/or post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines (surrogate)
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,19	0,19
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	5	5
Potential hand deposit	mg	4,60	4,60
penetration through gloves	%	100	10
Actual dermal deposit	mg	4,6	0,5
Total dermal exposure			
Total dermal deposit [a.s.]	mg	8,74E-03	8,74E-04
Penetration through skin [a.s.]	mg	1,05E-03	1,05E-04
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**1,75E-05**	**1,75E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,17**	**0,02**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**1,75E-05**	**1,75E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,17**	**0,02**

Cleaning of equipment such as dip/foam cups, trigger sprayer after use - 1x/day (post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines (surrogate)
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,56	0,56
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	5	5
Potential hand deposit	mg	4,60	4,60
penetration through gloves	%	100	10
Actual dermal deposit	mg	4,6	0,5
Total dermal exposure			
Total dermal deposit [a.s.]	mg	2,58E-02	2,58E-03
Penetration through skin [a.s.]	mg	3,09E-03	3,09E-04
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**5,15E-05**	**5,15E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,52**	**0,05**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**5,15E-05**	**5,15E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,52**	**0,05**

Cleaning of equipment such as dip/foam cups, trigger sprayer after use - 1x/day (post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines (surrogate)
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,72	0,72
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	5	5
Potential hand deposit	mg	4,60	4,60
penetration through gloves	%	100	10
Actual dermal deposit	mg	4,6	0,5
Total dermal exposure			
Total dermal deposit [a.s.]	mg	3,31E-02	3,31E-03
Penetration through skin [a.s.]	mg	3,97E-03	3,97E-04
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**6,62E-05**	**6,62E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,66**	**0,07**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**6,62E-05**	**6,62E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,66**	**0,07**

Cleaning of equipment such as dip/foam cups, trigger sprayer after use - 1x/day (post-milking)

Dermal exposure: RISKOFDERM toolkit, Connecting lines (surrogate)
Inhalation Exposure: not relevant, no exposure calculation required
According to HEAdhoc Recommendation no. 13 (Jan. 2017)

		Tier 1	Tier 2 gloves
Product	**Units**		
Density	g/ml	1	1
Active substance	% w/w	0,84	0,84
Body weight	kg	60	60
Dermal penetration rate	%	12	12
Dermal exposure			
Indicative value (hands)	mg/min	0,92	0,92
Duration	min	5	5
Potential hand deposit	mg	4,60	4,60
penetration through gloves	%	100	10
Actual dermal deposit	mg	4,6	0,5
Total dermal exposure			
Total dermal deposit [a.s.]	mg	3,86E-02	3,86E-03
Penetration through skin [a.s.]	mg	4,64E-03	4,64E-04
Number of applications	counts	1	1
Systemic exposure via dermal route	**mg/kg bw/day**	**7,73E-05**	**7,73E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,77**	**0,08**
Exposure by inhalation			
not relevant			
Total systemic exposure	**mg/kg bw/day**	**7,73E-05**	**7,73E-06**
Upper Intake Level (600 µg/person/day)	**mg/kg bw/day**	**0,01**	**0,01**
% Upper Intake Level	**%**	**0,77**	**0,08**

Combined exposure assessment professional uses including residues

Please refer to the confidential annex.

Consumer exposure: Dietary exposure to iodine residues

Please refer to the confidential annex.

Environmental risk assessment

Please refer to the confidential annex.

2.3. New information on the active substance

Not relevant. No new information available on iodine and PVP-iodine.

2.4. Residue behaviour

See chapter on exposure assessment for information on residues in milk.

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

See chapter 2.2.5 of this PAR on efficacy against target organisms as well as IUCLID file.

2.6. Confidential annex

Please refer to the separate document for the confidential annex.