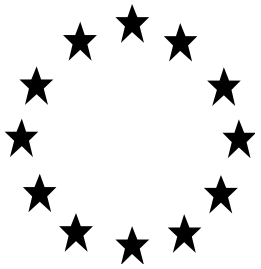
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product family identifier in R4BP	ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILY
Product type(s)	PT 03 (Veterinary hygiene)
Active ingredient(s)	Iodine
Case No.	BC-KY019330-22
Asset No.	DE-0013690-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/03.00001 710-05-03-00001-00-00-00-0000
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1 Conclusion

1.1 Conclusion regarding meta SPCs 1 to 4

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use products in meta SPC 1 to 4 of biocidal product family (BPF) "ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILY" with the active substance iodine (0.27 % w/w) are used for veterinary hygiene (product-type 03) for teat disinfection of milkable animals. The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled for meta SPCs 1 to 4. Please find detailed information on the uses appropriate for authorisation and directions for use in chapters 2.3 to 2.6.

A classification according to Regulation (EC) No 1272/2008[2] is necessary for meta SPCs 1, 2, 3 and 4.

The assessment of the intended uses as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Sweden Assessment Report for the approval of the active substance iodine including the "elements to be taken into account by Member States when authorising products" as requested by the Swedish CA.
2. The specific provisions from the approval decision for the active substance iodine (Commission Implementing Regulation (EU) No 94/2014).

Approval of the active substance

The active substance iodine is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- For products that may lead to residues in food or feed, 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, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Composition and formulation

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

The ready-to-use liquids contain the active substance iodine. The following substances of concern (SoC) were identified in meta SPC 2 and 4:

- isotridecanol, ethoxylated (CAS No. 69011-36-5)
- decan-1-ol, ethoxylated (CAS No. 26183-52-8)

Please refer to chapter 2.2 and chapter 5 (full composition; confidential Annex) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

Physical-chemical hazard(s) were not identified (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The products have been shown to be efficacious for the uses appropriate for authorisation listed in chapters 2.3 to 2.6. Please find more information on efficacy of the products in chapters 3.5.

Risk assessment for human health

A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses taken into account the identified SoC (see above).

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the instructions for use and risk mitigation measures according to chapters 2.3 to 2.6 are followed.

Risk assessment for the environment

Since no relevant SoC has been identified the risk assessment for the environment for this product is based on the active substance. The risk assessment for the environment has been carried out for professional use of the product (see chapter 3.8) for all intended uses.

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable risk for the environment if the instructions for use and risk mitigation measures according to chapters 2.3 to 2.6 are followed.

Comparative Assessment

Since the active substance iodine has not been identified as a candidate for substitution a comparative assessment was not necessary.

1.2 Conclusion regarding meta SPC 5

The assessment presented in this report has shown the efficacy but no unacceptable risks for human health, if the soluble concentrates in meta SPC 5 of biocidal product family (BPF) "ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILY" with the active substance iodine (2 % w/w) are used for veterinary hygiene (product-type 03) for surface disinfection of animal houses. The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[3] are fulfilled for meta SPC 5.

A classification according to Regulation (EC) No 1272/2008 is necessary for meta SPC 5.

The assessment of the intended uses as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

3. The conclusions and recommendations of the Sweden Assessment Report for the approval of the active substance iodine including the "elements to be taken into account by Member States when authorising products" as requested by the Swedish CA.
4. The specific provisions from the approval decision for the active substance iodine (Commission Implementing Regulation (EU) No 94/2014).

Approval of the active substance

The active substance iodine is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- For products that may lead to residues in food or feed, 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, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Composition and formulation

The soluble concentrates contain the active substance iodine. The following substances of concern (SoC) were identified in meta SPC 5:

- Orthophosphoric Acid (CAS No 7664-38-2)
- 2-(2-butoxyethoxy)ethanol (CAS No 112-34-5)
- Polyethylene glycol carboxymethyl dodecyl ether (CAS No. 27306-90-7)
- Alcohols, C12-15-branched and linear, ethoxylated, propoxylated (CAS No 120313-48-6)

[3] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

Please refer to chapter 2.2 and chapter 5 (full composition; confidential Annex) for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

The products have to be classified because of identified physical-chemical hazard(s) (see chapter 3.3). However, this does not lead to an unacceptable risk for end users.

Methods for detection and identification

Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The products have been shown to be efficacious for the uses appropriate for authorisation listed in chapters 2.3 to 2.6. Please find more information on efficacy of the products in chapters 3.5.

Risk assessment for human health

A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses taken into account the identified SoC (see above).

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable acute or chronic risk to bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the instructions for use and risk mitigation measures according to chapters 2.3 to 2.6 are followed.

Risk assessment for the environment

Since no relevant SoC has been identified the risk assessment for the environment for this product is based on the active substance. The risk assessment for the environment has been carried out for professional use of the product (see chapter 3.8) for all intended uses.

Based on the risk assessment it is unlikely that the intended uses cause any unacceptable risk for the environment if the instructions for use and risk mitigation are followed.

Comparative Assessment

Since the active substance iodine has not been identified as a candidate for substitution a comparative assessment was not necessary.

Overall conclusion

Overall, when exposure arising from biocides use is considered in isolation, no unacceptable risks are identified for professional users if appropriate PPE is worn or for the general public as a result of the consumer risk assessment.

When exposure from biocides use is considered in conjunction with total dietary exposure of iodine, acceptable risks may be identified for professional users if appropriate risk mitigation measures are in place and for adults following exposure to iodine in the diet. However, an unacceptable risk is identified for toddlers which is mainly due to exposure from non-biocidal sources of iodine accounting for 147% of the UL for toddlers.

The regulation of iodine exposure pathways that are not a consequence of biocidal use are outside the remit of the Biocidal Products Regulation. Unacceptable risks have been identified as a result of consideration of total dietary intake of iodine. It would be advisable that the issue is addressed at European level in order to ensure that all relevant regulatory bodies can be involved in agreeing a way forward.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILY

2.1.2 Product type(s)

PT 03 (Veterinary hygiene)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	ANTI-GERM Deutschland GmbH
Address of manufacturer	Oberbrühlstrasse 16-18 87700 Memmingen Germany
Location of manufacturing sites	Oberbrühlstrasse 16-18 87700 Memmingen Germany

Name of manufacturer	AG France SAS
Address of manufacturer	Zone industrielle Le Roineau 72500 Vaas France
Location of manufacturing sites	Zone industrielle Le Roineau 72500 Vaas France

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

Active substance	Iodine
Name of manufacturer	ANTI-GERM INTERNATIONAL GmbH
Address of manufacturer	Oberbrühlstr. 16-18 87700 MEMMINGEN Germany
Location of manufacturing sites	S.C.M. Cosayach Cala Cala Pozo Almonte Chile
Status of manufacturer	Reference source

Active substance	Iodine
Name of manufacturer	ANTI-GERM INTERNATIONAL GmbH
Address of manufacturer	Oberbrühlstr. 16-18 87700 MEMMINGEN Germany
Location of manufacturing sites	Lagunas mine Pozo Almonte Chile
Status of manufacturer	Reference source

Active substance	Iodine
Name of manufacturer	ANTI-GERM INTERNATIONAL GmbH
Address of manufacturer	Oberbrühlstr. 16-18 87700 MEMMINGEN Germany
Location of manufacturing sites	Nueva Victoria plant Pedro de Valdivia plant Chile
Status of manufacturer	Reference source

Active substance	Iodine
Name of manufacturer	Ise Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, Chuo-Ku Tokyo Japan
Location of manufacturing sites	Shirasato Plant 3695 Kitaimaizumi Oamishirasato City Chiba Japan

Status of manufacturer	Alternative iodine source, Technical equivalence has been established (Decision number: TAP-D-1184943-21-00/F)

Active substance	Iodine
Name of manufacturer	Atacama Minerals SCM
Address of manufacturer	Coronel Pereira No 72 Of. 701 Las Condes Santiago Chile
Location of manufacturing sites	Aguas Blancas Facility Antofagasta Chile
Status of manufacturer	Alternative iodine source Technical equivalence has been established (Decision number: TAP-D-1208508-26-00/F)

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition of the biocidal product family (active substance and substances of concern)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine*	Iodine	Active substance	7553-56-2	231-442-4	0.27	2.00
Isotridecanol, ethoxylated	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, branched	Non-active substance	69011-36-5	-	0	0.9945
1-Decanol, ethoxylated (8 EO)	1-Decanol, ethoxylated	Non-active substance	26183-52-8	-	0	0.9
Phosphoric acid	orthophosphoric acid	Non-active substance	7664-38-2	231-633-2	0	9.12
Laureth-11 carboxylic acid	Polyethylene glycol carboxymethyl dodecyl ether	Non-active substance	27306-90-7	-	0	6.66
Butyl diglycol	2-(2-Butoxyethoxy) ethanol	Non-active substance	112-34-5	203-961-6	0	6
Alcohols, C12-15-branched and linear, ethoxylated propoxylated	-	Non-active substance	120313-48-6	-	0	2

* Iodine is added to the BPF as formulation; the stated amount is equal to pure Iodine respectively added Iodine content based of Iodine included in the formulations.

As the products and meta SPC are containing only one iodine source, no further iodate oder iodide is added and the available iodine content is equal to the total iodine content.

Information on the full composition of the BPF is provided in the confidential[4] annex

According to the information provided the products in the BPF contain no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

Three sources of the active substance are the same as the ones evaluated in connection with the active substance approval. For two new sources technical equivalence of the active substance was established by ECHA (see decision numbers TAP-D-1184943-21-00/F and TAP-D-1208508-26-00/F).

2.2.3 Information on the substance(s) of concern (SoC)

The following substances of concern (SoC) were identified in the BPF as applied for (meta SPCs 1-5):

- isotridecanol, ethoxylated (CAS No. 69011-36-5) in meta SPC 2 and 4
- decan-1-ol, ethoxylated (CAS No. 26183-52-8) in meta SPC 2 and 4
- Orthophosphoric Acid (CAS No 7664-38-2) in meta SPC 5
- 2-(2-butoxyethoxy)ethanol (CAS No 112-34-5) in meta SPC 5)
- Polyethylene glycol carboxymethyl dodecyl ether (CAS No. 27306-90-7) in meta SPC 5
- Alcohols, C12-15-branched and linear, ethoxylated, propoxylated (CAS No 120313-48-6) in meta SPC 5

Identification is based on the classification of the substance of concerns as Corr. 1B (orthophosphoric acid), Eye Dam. 1 (isotridecanol, ethoxylated; decan-1-ol, ethoxylated; polyethylene glycol carboxymethyl dodecyl ether), Skin Irrit. 2 (polyethylene glycol carboxymethyl dodecyl ether; alcohols, C12-15-branched and linear, ethoxylated propoxylated) and Eye Irrit. 2 (2-(2-butoxyethoxy)ethanol), their concentration in the biocidal products and their contribution to the classification of the biocidal products as Skin Irrit. 2 and/or Eye Irrit. 2.
The biocidal products of meta SPC 5 are used as dilution (2 %) of the biocidal product in water. In this concentration the corresponding substances of concern (and the active substance) do not trigger classification as Skin Irrit. 2 and/or Eye Irrit. 2.

2.2.4 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.5 Type(s) of formulation

Any other liquid (ready-to-use (meta SPC 1-4), soluble concentrate (meta SPC 5))

[4] Access level: “Restricted” to applicant and authority

2.3 Meta SPC No. 1 (second information level)

2.3.1 Administrative information

2.3.1.1 *Meta SPC identifier*

Meta SPC 1

2.3.1.2 *Suffix to the authorisation number*

01

2.3.1.3 *Product type(s) of the meta SPC*

PT 03 (Veterinary hygiene)

2.3.2 Composition and formulation of the meta SPC

2.3.2.1 *Qualitative and quantitative information on the composition of the meta SPC*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.27	0.27

2.3.2.2 *Type(s) of formulation of the meta SPC*

Any other liquid (ready-to-use)

2.3.3 Classification and Labelling of the meta SPC according to the Regulation (EC) 1272/2008

The content of iodine in the products in the meta SPC 1 acounts to 0,27%. Based on this iodine content and in accordance with Regulation (EC) No 1272/2008 the biocidal products in the meta SPC 1 have to be classified as H412 (Harmful to aquatic life with long lasting effects).

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Aquatic chronic, category 3	H412	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	-	-
Signal word	-	-
Hazard statements	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P273	Avoid release to the environment.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-	-

2.3.4 Use(s) of the meta SPC appropriate for authorisation

2.3.4.1 *Use 1.1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment

	Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.3.4.1.1 Use-specific instructions for use

1) A no-spill dip cup should be used for manual teat dipping.
2) Fill the reservoir with the RTU product and screw the dip cup on top.
3) The product must be brought to a temperature above 20 °C before use.
4) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
5) After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
6) Top up with fresh disinfectant as needed.
7) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
8) After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

2.3.4.1.2 Use-specific risk mitigation measures

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

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

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

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

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2.3.4.2 *Use 1.2 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 4 - 5 mL/treatment Sheep: 2 – 2.5 mL/treatment Goats: 2.5 – 3 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.3.4.2.1 Use-specific instructions for use

1) Fill the reservoir with the RTU product and screw the foam cup on top.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
4) After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
5) Top up with fresh disinfectant as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

2.3.4.2.2 Use-specific risk mitigation measures

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

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

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

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

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2.3.4.3 *Use 1.3 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.3.4.3.1 Use-specific instructions for use

1) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
4) After milking, spray the disinfectant on the teats using the trigger sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.
5) Top up with fresh disinfectant as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

2.3.4.3.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:

   Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

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

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

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

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2.3.4.4 *Use 1.4 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.3.4.4.1 Use-specific instructions for use

1) Open a can containing the RTU product and insert a sucking lance of the electronic sprayer.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean carefully the teats by wiping with a single service paper towel/cloth before milking.
4) After milking, spray the disinfectant on the teats using the electronic sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.
5) Replace the empty can by a new can containing the RTU product as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

2.3.4.4.2 Use-specific risk mitigation measures

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

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

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

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

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2.3.4.5 *Use 1.5 – Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.3.4.5.1 Use-specific instructions for use

1) Open a can containing the RTU product and insert a sucking lance of the robotic milking device.
2) The product must be brought to a temperature above 20 °C before use.
3) The teats are cleaned by robot with automatic brushes.
4) After robotic milking, the disinfectant is sprayed automatically onto the teats from a cluster arm.
5) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
6) Rinsing of the automatic sprayer is done fully automated.

2.3.4.5.2 Use-specific risk mitigation measures

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

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

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

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

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2.3.5 General directions for use of the meta SPC

2.3.5.1 *Instructions for use*

See use specific instructions for use.

2.3.5.2 *Risk mitigation measures*

1) Keep out of reach of children. 2) When pre-milking disinfection is also performed, then disinfection should be done with a product based on another active substance (not iodine).

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

1) In case of spillage or leakage contain and collect product for disposal. 2) Disposal must comply with local requirements.

2.3.5.4 *Instructions for safe disposal of the product and its packaging*

1) At the end of the treatment, dispose unused product, used paper towels and the packaging in accordance with local requirements. 2) Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. 3) Avoid release to an individual waste water treatment plant.

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

1) Do not store at temperatures above 30^{o}C.
2) Shelf-life of 18 months.

2.3.6 Other information

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2.4 Meta SPC No. 2 (second information level)

2.4.1 Administrative information

2.4.1.1 *Meta SPC identifier*

Meta SPC 2

2.4.1.2 *Suffix to the authorisation number*

02

2.4.1.3 *Product type(s) of the meta SPC*

PT 03 (Veterinary hygiene)

2.4.2 Composition and formulation of the meta SPC

2.4.2.1 *Qualitative and quantitative information on the composition of the meta SPC*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.27	0.27
Isotridecanol, ethoxylated	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, branched	Non-active substance	69011-36-5	-	0.9815	0.9945
1-Decanol, ethoxylated (8 EO)	1-Decanol, ethoxylated	Non-active substance	26183-52-8	-	08	0.9

2.4.2.2 *Type(s) of formulation of the meta SPC*

Any other liquid (ready-to-use)

2.4.3 Classification and Labelling of the meta SPC according to the Regulation (EC) 1272/2008

The products in the meta SPC contain two co-formulants which are classified as Eye Dam H318 in concentration of < 1 % but in sum above 1 %. Based on this components and in accordance to Regulation (EC) No 1272/2008 and the principle of additivity the biocidal products in the meta SPC have to be classified as Eye Irrit. 2, H319. For details see chapter 3.6.2.2.

The content of iodine in the products in the meta SPC 2 acounts to 0,27%. Based on this iodine content and in accordance with Regulation (EC) No 1272/2008 the biocidal products in the meta SPC 2 have to be classified as H412 (Harmful to aquatic life with long lasting effects).

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Eye Irrit. 2	H319	
Aquatic chronic, category 3	H412	
Labelling		
	Code	**Pictogram / Wording**
Pictograms	GHS07	
Signal word	-	Warning
Hazard statements	H319	Causes serious eye irritation
	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves/eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P273	Avoid release to the environment.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-	-

Low hazard category applies for local effects risk assessment for the undiluted product.

2.4.4 Use(s) of the meta SPC appropriate for authorisation

2.4.4.1 *Use 2.1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.4.4.1.1 Use-specific instructions for use

1) A no-spill dip cup should be used for manual teat dipping.
2) Fill the reservoir with the RTU product and screw the dip cup on top.
3) The product must be brought to a temperature above 20 °C before use.
4) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
5) After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
6) Top up with fresh disinfectant as needed.
7) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.

8) After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

2.4.4.1.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   The use of eye protection during handling of the product is mandatory.
2) The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

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

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2.4.4.2 *Use 2.2 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual foaming using a foam cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 4 - 5 mL/treatment Sheep: 2 – 2.5 mL/treatment Goats: 2.5 – 3 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.4.4.2.1 Use-specific instructions for use

1) Fill the reservoir with the RTU product and screw the foam cup on top.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
4) After milking, squeeze the reservoir and put the foam cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
5) Top up with fresh disinfectant as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, empty the reservoir and clean reservoir and foam cup by rinsing with water.

2.4.4.2.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   The use of eye protection during handling of the product is mandatory.
2) The use of a dosing pump for filling the product into the application equipment is recommended.

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

-

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

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

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2.4.4.3 *Use 2.3 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual spraying using a trigger sprayer
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.4.4.3.1 Use-specific instructions for use

1) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
4) After milking, spray the disinfectant on the teats using the trigger sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.
5) Top up with fresh disinfectant as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

2.4.4.3.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   a) The use of eye protection during handling of the product is mandatory.
   b) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
2) The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

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

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2.4.4.4 *Use 2.4 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual spraying using an electronic sprayer
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.4.4.4.1 Use-specific instructions for use

1) Open a can containing the RTU product and insert a sucking lance of the electronic sprayer.
2) The product must be brought to a temperature above 20 °C before use.
3) Clean carefully the teats by wiping with a single service paper towel/cloth before milking.
4) After milking, spray the disinfectant on the teats using the electronic sprayer making sure that the full length of the teat (3-5 cm) is covered with the disinfectant.
5) Replace the empty can by a new can containing the RTU product as needed.
6) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
7) After disinfection, put the sucking lance system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

2.4.4.4.2 Use-specific risk mitigation measures

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:
   The use of eye protection during handling of the product is mandatory.
2) The use of a dosing pump for filling the product into the application equipment is recommended.

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

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

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

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2.4.4.5 *Use 2.5 – Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Automated spraying by robot
Application rate(s) and frequency	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.4.4.5.1 Use-specific instructions for use

1) Open a can containing the RTU product and insert a sucking lance of the robotic milking device.
2) The product must be brought to a temperature above 20 °C before use.
3) The teats are cleaned by robot with automatic brushes.
4) After robotic milking, the disinfectant is sprayed automatically onto the teats from a cluster arm.
5) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.
6) Rinsing of the automatic sprayer is done fully automated.

2.4.4.5.2 Use-specific risk mitigation measures

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

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

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

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

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2.4.5 General directions for use of the meta SPC

2.4.5.1 *Instructions for use*

See use-specific instructions for use

2.4.5.2 *Risk mitigation measures*

1) Keep out of reach of children. 2) When pre-milking disinfection is also performed, then disinfection should be done with a product based on another active substance (not iodine).

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

1) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 2) If eye irritation persists: Get medical advice/attention. 3) In case of spillage or leakage contain and collect product for disposal. Disposal must comply with local requirements.

2.4.5.4 *Instructions for safe disposal of the product and its packaging*

1) At the end of the treatment, dispose unused product, used paper towels and the packaging in accordance with local requirements.

2) Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements.
3) Avoid release to an individual waste water treatment plant.

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

1) Do not store at temperatures above 30^{o}C.
2) Shelf-life of 18 months.

2.4.6 Other information

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2.5 Meta SPC No. 3 (second information level)

2.5.1 Administrative information

2.5.1.1 *Meta SPC identifier*

Meta SPC 3

2.5.1.2 *Suffix to the authorisation number*

03

2.5.1.3 *Product type(s) of the meta SPC*

PT 03 (Veterinary hygiene)

2.5.2 Composition and formulation of the meta SPC

2.5.2.1 *Qualitative and quantitative information on the composition of the meta SPC*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.27	0.27

2.5.2.2 *Type(s) of formulation of the meta SPC*

Any other liquid (ready-to-use)

2.5.3 Classification and Labelling of the meta SPC according to the Regulation (EC) 1272/2008

The content of iodine in the products in the meta SPC 3 acounts to 0,27%. Based on this iodine content and in accordance with Regulation (EC) No 1272/2008 the biocidal products in the meta SPC 3 have to be classified as H412 (Harmful to aquatic life with long lasting effects).

Classification Hazard classes, Hazard categories	Hazard statements	
Aquatic chronic, category 3	H412	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	-	-
Signal word	-	-
Hazard statements	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P273	Avoid release to the environment.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-	-

2.5.4 Use(s) of the meta SPC appropriate for authorisation

2.5.4.1 *Use 3.1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users

Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.5.4.1.1 Use-specific instructions for use

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2.5.4.1.2 Use-specific risk mitigation measures

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

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

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

-

2.5.5 General directions for the meta SPC

2.5.5.1 *Instructions for use*

1) A no-spill dip cup should be used for manual teat dipping.
2) Fill the reservoir with the RTU product and screw the dip cup on top.
3) The product must be brought to a temperature above 20 °C before use.
4) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking.
5) After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant.
6) Top up with fresh disinfectant as needed.
7) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking.

8) After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

2.5.5.2 *Risk mitigation measures*

1) The use of a dosing pump for filling the product into the application equipment is recommended.
2) Keep out of reach of children.
3) When pre-milking disinfection is also performed, then disinfection should be done with a product based on another active substance (not iodine).

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

1) In case of spillage or leakage contain and collect product for disposal.
2) Disposal must comply with local requirements.

2.5.5.4 *Instructions for safe disposal of the product and its packaging*

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

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

1) Do not store at temperatures above 30^{o}C.
2) Shelf-life of 18 months.

2.5.6 Other information

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2.6 Meta SPC No. 4 (second information level)

2.6.1 Administrative information

2.6.1.1 *Meta SPC identifier*

Meta SPC 4

2.6.1.2 *Suffix to the authorisation number*

04

2.6.1.3 *Product type(s) of the meta SPC*

PT 03 (Veterinary hygiene)

2.6.2 Composition and formulation of the meta SPC

2.6.2.1 *Qualitative and quantitative information on the composition of the meta SPC*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	0.27	0.27
Isotridecanol, ethoxylated	Poly(oxy-1,2-ethanediyl), α-tridecyl-ω-hydroxy-, branched	Non-active substance	69011-36-5	-	0.9815	0.9945
1-Decanol, ethoxylated (8 EO)	1-Decanol, ethoxylated	Non-active substance	26183-52-8	-	0.8	0.9

2.6.2.2 *Type(s) of formulation of the meta SPC*

Any other liquid (ready-to-use)

2.6.3 Classification and Labelling of the meta SPC according to the Regulation (EC) 1272/2008

The products in the meta SPC contain two co-formulants which are classified as Eye Dam H318 in concentration of < 1 % but in sum above 1 %. Based on this components and in accordance to Regulation (EC) No 1272/2008 and the principle of additivity the biocidal product in the meta SPC have to be classified as Eye Irrit. 2, H319. For details see chapter 3.6.2.2.

The content of iodine in the products in the meta SPC 4 acounts to 0,27%. Based on this iodine content and in accordance with Regulation (EC) No 1272/2008 the biocidal products in the meta SPC 4 have to be classified as H412 (Harmful to aquatic life with long lasting effects).

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Eye Irrit. 2	H319	
Aquatic chronic, category 3	H412	
Labelling		
	Code	**Pictogram / Wording**
Pictograms	GHS07	
Signal word	-	Warning
Hazard statements	H319	Causes serious eye irritation
	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P264	Wash hands horoughly after handling.
	P280	Wear eye protection.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337 + P313	If eye irritation persists: Get medical advice/attention.
	P273	Avoid release to the environment.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note	-	-

Low hazard category applies for local effects risk assessment for the ready-to-use product.

2.6.4 Use(s) of the meta SPC appropriate for authorisation

2.6.4.1 *Use 4.1 – Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping*

Product Type(s)	03
Where relevant, an exact description of the use	Not relevant
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor use
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.6.4.1.1 Use-specific instructions for use

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2.6.4.1.2 Use-specific risk mitigation measures

-

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

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

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

-

2.6.5 General directions for use of the meta SPC

2.6.5.1 *Instructions for use*

1) A no-spill dip cup should be used for manual teat dipping. 2) Fill the reservoir with the RTU product and screw the dip cup on top. 3) The product must be brought to a temperature above 20 °C before use. 4) Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. 5) After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat (3-5 cm) is immersed into the disinfectant. 6) Top up with fresh disinfectant as needed. 7) Keep the animals standing for at least five minutes after treatment. Leave the product on the teats until next milking. 8) After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

2.6.5.2 *Risk mitigation measures*

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures: The use of eye protection during handling of the product is mandatory. 2) The use of a dosing pump for filling the product into the application equipment is recommended. 3) Keep out of reach of children. 4) When pre-milking disinfection is also performed, then disinfection should be done with a product based on another active substance (not iodine).

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

1) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
2) If eye irritation persists: Get medical advice/attention.
3) In case of spillage or leakage contain and collect product for disposal. Disposal must comply with local requirements.

2.6.5.4 *Instructions for safe disposal of the product and its packaging*

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

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

1) Do not store at temperatures above 30^{o}C.
2) Shelf-life of 18 months.

2.6.6 Other information

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2.7 Meta SPC No. 5 (second information level)

2.7.1 Administrative information

2.7.1.1 *Meta SPC identifier*

Meta SPC 5

2.7.1.2 *Suffix to the authorisation number*

05

2.7.1.3 *Product type(s) of the meta SPC*

PT 03 (Veterinary hygiene)

2.7.2 Composition and formulation of the meta SPC

2.7.2.1 *Qualitative and quantitative information on the composition of the meta SPC*

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine	Iodine	Active substance	7553-56-2	231-442-4	2	2
Phosphoric acid	Orthophos-phoric acid	Non-active substance	7664-38-2	231-633-2	7.992	9.12
Laureth-11 carboxylic acid	Polyethylene glycol carboxymethyl dodecyl ether	Non-active substance	27306-90-7	-	6.46	6.66
Butyl diglycol	2-(2-Butoxyethoxy) ethanol	Non-active substance	112-34-5	203-961-6	5	6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
Alcohols, C12-15-branched and linear, ethoxylated propoxylated	-	Non-active substance	120313-48-6	-	1.8	2

2.7.2.2 *Type(s) of formulation of the meta SPC*

Soluble concentrate

2.7.3 Classification and Labelling of the meta SPC according to the Regulation (EC) 1272/2008

The products in the meta SPC contain several co-formulants which are classified for skin corrosion, eye damage and eye irritation in relevant concentration. Based on these components and in accordance to Regulation (EC) No 1272/2008 and the principle of additivity the biocidal products have to be classified as Skin Irrit. 2 H315 and Eye Dam. 1, H318.
Based on the experimental data on the product in the meta SPC, which is corrosive to metals according to the classification criteria, the biocidal products have to be classified as Met. Corr. 1 H290. For details see chapters 3.3 and 3.6.2.2.
The content of iodine in the products in the meta SPC 5 acounts to 2%. Based on this iodine content and in accordance with Regulation (EC) No 1272/2008 the biocidal products in the meta SPC 5 have to be classified as H412 (Harmful to aquatic life with long lasting effects).

Classification **Hazard classes, Hazard categories**	**Hazard statements**	
Met. Corr. 1	H290	
Skin Irrit. 2	H315	
Eye Dam. 1	H318	
Aquatic chronic, category 3	H412	
Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS05	
	GHS07	
Signal word	-	Danger

Hazard statements	H290	May be corrosive to metals.
	H315	Causes skin irritation.
	H318	Causes serious eye damage.
	H412	Harmful to aquatic life with long lasting effects
Supplemental hazard information	-	-
Supplemental label elements	-	-
Precautionary statements	P234	Keep only in original container.
	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P302 + P352	IF ON SKIN: Wash with plenty of water.
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P332 + P313	If skin irritation occurs: Get medical advice/attention.
	P310	Immediately call a POISON CENTER/ doctor/... …Manufacturer/supplier to specify the appropriate source of emergency medical advice.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P273	Avoid release to the environment.
	P501	Dispose of contents/containers in accordance with local/regional/national/international regulation.
Note		

The hazard category for local effects risk assessment of undiluted product is low.
The in-use dilution of the biocidal product (2 % of the biocidal product in water) do not require classification, therefore no risk assessment for local effects is required.

2.7.4 Use(s) of the meta SPC appropriate for authorisation

2.7.4.1 *Use 5.1 – Disinfection of animal houses by manual spraying*

<table>
<tr><td>Product Type(s)</td><td>03</td></tr>
<tr><td>Where relevant, an exact description of the use</td><td>Not relevant</td></tr>
<tr><td>Target organism(s) (including development stage)</td><td>bacteria, yeast, viruses</td></tr>
<tr><td>Field(s) of use</td><td>Disinfection for veterinary hygiene: Disinfection of clean non-porous surfaces in animal houses of sows, fattening pigs and poultry (laying hens, broilers, turkeys, ducks and geese)

Indoor use</td></tr>
<tr><td>Application method(s)</td><td>Manual spraying</td></tr>
<tr><td>Application rate(s) and frequency</td><td>Application rates (all under application frequency listed animal species):
400 mL/m^2

<table>
<tr><td>Target Organism</td><td></td></tr>
<tr><td>Bacteria</td><td>1 % dilution of the concentrate (one part of concentrate to 100 parts of water, i.e. 0,02 % available iodine)
Contact time: 30 min</td></tr>
<tr><td>Yeast</td><td>1 % dilution of the concentrate (one part of concentrate to 100 parts of water, i.e. 0,02 % available iodine)
Contact time: 60 min</td></tr>
<tr><td>Viruses</td><td>2% dilution of the concentrate (one part of concentrate to 50 parts of water, i.e. 0,04 % available iodine)
Contact time: 60 min</td></tr>
</table>

Application frequency:
- Sows in individual pens: 8/year
- Sows in groups:1/year
- Fattening pigs: 2/year
- Laying hens: 1/year
- Broilers: 1-8/year
- Turkeys: 2/year
- Ducks: 10/year</td></tr>
</table>

	- Geese: 2/year
Category(ies) of users	Professional users
Pack sizes and packaging material	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

2.7.4.1.1 Use-specific instructions for use

Avoid contamination of feed, water, feeding and drinking equipment during application of the product.

2.7.4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.7.5 General directions for use of the meta SPC

2.7.5.1 *Instructions for use*

1) Decant or pump the concentrated product and dilute with water to yield an in-use solution of 1% (bacteria and yeast) or 2% (viruses) of the concentrate. 2) Fill the reservoir of the knapsack sprayer (low pressure spray) with the diluted concentrate. 3) Clean surfaces before application of the product. 4) Spray the disinfectant making sure surfaces are thoroughly wetted and leave to dry. The contact time should be at least 30 minutes (bacteria) or 60 minutes (yeast, viruses)

respectively.

5) After disinfection, empty the reservoir and clean reservoir and the spray equipment by rinsing with water.

2.7.5.2 *Risk mitigation measures*

1) The following personal risk mitigation measures shall be applied unless they can be replaced by technical and / or organisational measures:

a) The use of eye protection during handling of the product is mandatory.

b) Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

c) A protective coverall (at least type 6, EN 13034) shall be worn.

2) Apply biocidal product in the absence of livestock animals. Wait until treated areas are dried before re-entry of livestock animals.

3) No access to treated areas for uninvolved third parties (general public) and pets until surfaces are dried.

4) Keep out of reach of children.

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

1) IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
2) If eye irritation persists: Get medical advice/attention.
3) IF ON SKIN: Wash with plenty of water.
4) If skin irritation occurs: Get medical advice/attention.
5) Take off contaminated clothing and wash it before reuse.
6) In case of spillage or leakage contain and collect product for disposal. Disposal must comply with local requirements.

2.7.5.4 *Instructions for safe disposal of the product and its packaging*

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

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

1) Do not store at temperatures above 30^{o}C.
2) Keep only in original container.
3) Store in a corrosive resistant container with a resistant inner liner.
4) Shelf-life: 18 months.

2.7.6 Other information

-

2.8 Individual products in the meta SPC(s) (third information level)

Information on the specific composition of each individual product is provided in the confidential annex.

2.9 Packaging

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Jerrycan	1-35 kg	HDPE	Tamper evidence cap, HDPE	professional	Yes
Drum	35-240 kg	HDPE	Tab-seal cap, HDPE	professional	Yes
IBC	1000 kg	HDPE	IBC: Notch seal, HDPE	professional	Yes

3 Assessment of the biocidal product family

3.1 Intended use(s) as applied for by the applicant[5]

3.1.1 meta SPC 1

Use	Use name	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organism(s) (including develop-ment stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1.1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual dipping using a dip cup	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

[5] With letter of 11.05.2016 the applicant **withdrew the original application** for meta SPC 6 (product type 04; disinfection of milking machine systems, other milking equipment and bulk milk storage tanks).

1.2	Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual foaming using a foam cup	Application rates: Cows and buffaloes: 4 - 5 mL/treatment Sheep: 2 – 2.5 mL/treatment Goats: 2.5 – 3 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg
1.3	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual spraying using a trigger sprayer	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

1.4	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual spraying using an electronic sprayer	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg
1.5	Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Automated spraying by robot	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

3.1.2 meta SPC 2

Use	Use name	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and pack-aging material
1.1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual dipping using a dip cup	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

1.2	Teat disinfection of milkable animals: Post-milking teat disinfection by manual foaming	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual foaming using a foam cup	Application rates: Cows and buffaloes: 4 - 5 mL/treatment Sheep: 2 – 2.5 mL/treatment Goats: 2.5 – 3 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg
1.3	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual spraying using a trigger sprayer	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

1.4	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual spraying using an electronic sprayer	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg
1.5	Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Automated spraying by robot	Application rates: Cows and buffaloes: 12 – 15 mL/treatment Sheep: 6 – 7.5 mL/treatment Goats: 7 – 9 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

3.1.3 meta SPC 3

Use	Use name	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1.1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual dipping using a dip cup	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

3.1.4 meta SPC 4

Use	Use name	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material
1.1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping	Any other liquid (AL)	PT 03	not relevant	bacteria, yeast	Disinfection for veterinary hygiene: teat disinfection for milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking Indoor and outdoor	Manual dipping using a dip cup	Application rates: Cows and buffaloes: 8 - 10 mL/treatment Sheep: 4 – 5 mL/treatment Goats: 5 – 6 mL/treatment Application frequency: Post-milking application: 1 – 3x/day (after each milking)	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

3.1.5 meta SPC 5

Use	Use name	Type(s) of formulation	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category of users	Pack sizes and packaging material

2.1	Disinfection of animal houses by manual spraying	Soluble concentrate (SL)	PT 03	not relevant	bacteria, yeast, viruses	Disinfection for veterinary hygiene: Surface disinfection in animal houses Indoor	Manual spraying	Application rates (all animal species): 400 mL/m2 Concentrate: 2% available iodine In-use dilution: 1%-2% solution of the concentrate (0.02 – 0.04% available iodine) 1% solution: Dilute 1 part concentrate to 100 parts water yielding an in-use concentration of 0.02% available iodine. 2% solution: Dilute 1 part concentrate to 50 parts water yielding an in-use concentration of 0.04% available iodine. Application frequency: - Sows in individual pens: 8/year - Sows in groups: 1/year - Fattening pigs: 2/year - Laying hens: 1/year - Broilers: 1-8/year - Turkeys: 2/year - Ducks: 10/year - Geese: 2/year	Professional user	Jerrycan (HDPE): 1-35 kg Drum (HDPE): 35-240 kg IBC (HDPE): 1000 kg

3.2 Physical, chemical and technical properties

Table 1: Physical, chemical and technical properties of the biocidal product family (BPF)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	0.27 - 2.00 % (w/w) Iodine (all products)	Liquid	▫ Demangel, B. (2015), Report no. 15-909024-017 ▫ Demangel, B. (2015), Report no. 15-909024-002 ▫ Demangel, B. (2015), Report no. 15-909024-023 ▫ Demangel, B. (2015), Report no. 15-909024-007 ▫ Demangel, B. (2015), Report no. 15-909024-012
Colour at 20 °C and 101.3 kPa	Visual assessment	0.27 - 2.00 % (w/w) Iodine (all products)	Brown	
Odour at 20 °C and 101.3 kPa	Olfactory inspection	0.27 - 2.00 % (w/w) Iodine (all products)	Typical iodine odour	
Acidity / alkalinity	pH value: CIPAC MT 75; Acidity: CIPAC MT191	0.27 - 2.00 % (w/w) Iodine (all products)	pH = ca. 2.08 – 4.13 (20°C) Acidity = ca. 0.031% (w/w) – 10.10% (w/w) For more information on the acceptable range of pH of the different products/meta SPCs please refer to the confidential annex of the PAR.	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	pH = 3.94 (at 21.2°C) [after 1 min] pH = 3.93 (at 21.2°C) [after 2 min] Acidity = 0.083% (w/w)	Demangel, B. (2015) Report no. 15-909024-020
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	pH = 3.88 (at 20.0°C) [after 1 min] pH = 3.88 (at 20.0°C) [after 2 min] Acidity = 0.031% (w/w)	Demangel, B. (2015) Report no. 15-909024-005
		ANTI-GERM IO-FILM	Read-across: Product is very similar in	Read-across to tested teat

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(specified a.s. content: 0.27% (w/w) Iodine)	composition to the 5 tested teat disinfection products; A pH of around 4 is expected.	disinfection products
		ANTI-GERM IO-BAR (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine)	pH = 4.13 (at 20.5°C) [after 1 min] pH = 4.12 (at 20.6°C) [after 2 min] Acidity: n.a.; 4 < pH < 10	Demangel, B. (2015) Report no. 15-909024-026
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	pH = 4.00 (at 20.2°C) [after 1 min] pH = 3.99 (at 20.2°C) [after 2 min] Acidity = 0.043% (w/w)	Demangel, B. (2015) Report no. 15-909024-010
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	pH = 3.91 (at 20.5°C) [after 1 min] pH = 3.89 (at 20.7°C) [after 2 min] Acidity = 0.093% (w/w)	Demangel, B. (2015) Report no. 15-909024-015
		GERMICIDAN® IODES (Lot number: 15072801) 2.04% (w/w) Iodine	pH = 2.11 (at 24.3°C) [after 1 min] pH = 2.08 (at 24.3°C) [after 2 min] Acidity = 10.10% (w/w)	Mayer, P. (2016) Report no. AT 09.02.01
Relative density / bulk density	EU Method A.3; OECD Guideline 109	0.27 - 2.00 % (w/w) Iodine (all products)	D^4_{20} = ca. 1.021 – 1.1	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	D^4 = 1.024 ± 0.001 (at 19.9°C)	Demangel, B. (2015) Report no. 15-909024-016
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	D^4 = 1.021 ± 0.001 (at 21.6°C)	Demangel, B. (2015) Report no. 15-909024-001
		ANTI-GERM IO-FILM (specified a.s. content: 0.27% (w/w) Iodine)	Read-across: Product is very similar in composition to the 5 tested teat disinfection products. A relative density between 1.02 and 1.05 is expected.	Read-across to tested teat disinfection products

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		ANTI-GERM IO-BAR (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine)	D^4 = 1.035 ± 0.001 (at 21.4°C)	Demangel, B. (2015) Report no. 15-909024-022
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	D^4 = 1.022 ± 0.002 (at 21.4°C)	Demangel, B. (2015) Report no. 15-909024-006
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	D^4 = 1.044 ± 0.001 (at 21.5°C)	Demangel, B. (2015) Report no. 15-909024-011
		GERMICIDAN® IODES (Lot number: 15111901) 2.02% (w/w) Iodine	D_4^{20} = 1.0753 ± 0.0001	Mayer, P. (2016) Report no. AT 09.02.05
Storage stability test – **accelerated storage**	CIPAC MT 46.3	0.27 - 2.00 % (w/w) Iodine (all products)	see below	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	The product is expected to be stable at 30°C for 9 weeks. Iodine content decrease >10% w/w after 18 weeks at 30°C; an appropriate label phrase is required to indicate that the biocidal product must not be stored at higher temperatures. <u>Iodine content:</u> ▫ T(0) = 0.278% (w/w) ▫ T(9 weeks) = 0.252% (w/w) (90.6% of T(0)) ▫ T(18 weeks) = 0.232% (w/w) (83.5% of T(0))	Demangel, B. (2015) Report no. 15-909024-020

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Iodide content: ▫ T(0) = 0.026% (w/w) ▫ T(9 weeks) = 0.042% (w/w) (161.5% of T(0)) ▫ T(18 weeks) = 0.059% (w/w) (226.9% of T(0)) Iodate content: ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(9 weeks) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 weeks) = not detectable in test item [<0.0049% (w/w)] pH value and acidity of test item: stable	
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	Product stable at 30°C for 18 weeks Iodine content: ▫ T(0) = 0.271% (w/w) ▫ T(9 weeks) = 0.256% (w/w) (94.5% of T(0)) ▫ T(18 weeks) = 0.246% (w/w) (90.8% of T(0)) Iodide content: ▫ T(0) = 0.044% (w/w) ▫ T(9 weeks) = 0.058% (w/w) (131.8% of T(0))	Demangel, B. (2015) Report no. 15-909024-005

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(18 weeks) = 0.066% (w/w) (150.0% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(9 weeks) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 weeks) = not detectable in test item [<0.0049% (w/w)] pH value and acidity of test item: stable	
		ANTI-GERM IO-FILM (specified a.s. content: 0.27% (w/w) Iodine)	Read-across: Product is very similar in composition to the 5 tested teat disinfection products. The product is expected to be stable at 30°C for 9 weeks. For four of the five tested teat disinfection products (ANTI-GERM IO-SPRAY, ANTI-GERM IO-BAR, ANTI-GERM IO-FILM-27 and ANTI-GERM IO-BAR-27) the Iodine content decrease is >10% w/w after 18 weeks at 30°C, therefore it cannot be expected that the product ANTI-GERM IO-FILM is stable at 30°C for 18 weeks; an appropriate label phrase is required to indicate that the biocidal product must not be stored at higher temperatures.	Read-across to tested teat disinfection products
		ANTI-GERM IO-BAR	The product is expected to be stable at	Demangel, B. (2015)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine)	30°C for 9 weeks. Iodine content decrease >10% w/w after 18 weeks at 30°C; an appropriate label phrase is required to indicate that the biocidal product must not be stored at higher temperatures. Iodine content: ▫ T(0) = 0.281% (w/w) ▫ T(9 weeks) = 0.261% (w/w) (92.9% of T(0)) ▫ T(18 weeks) = 0.235% (w/w) (83.6% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.035% (w/w) ▫ T(9 weeks) = 0.050% (w/w) (142.9% of T(0)) ▫ T(18 weeks) = 0.078% (w/w) (222.9% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(9 weeks) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 weeks) = not detectable in test item [<0.0049% (w/w)]	Report no. 15-909024-026

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH value and acidity of test item: stable	
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	The product is expected to be stable at 30°C for 9 weeks. Iodine content decrease >10% w/w after 18 weeks at 30°C; an appropriate label phrase is required to indicate that the biocidal product must not be stored at higher temperatures. Iodine content: ▫ T(0) = 0.275% (w/w) ▫ T(9 weeks) = 0.250% (w/w) (90.9% of T(0)) ▫ T(18 weeks) = 0.226% (w/w) (82.2% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.042% (w/w) ▫ T(9 weeks) = 0.067% (w/w) (159.5% of T(0)) ▫ T(18 weeks) = 0.089% (w/w) (211.9% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(9 weeks) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 weeks) = not detectable in test item	Demangel, B. (2015) Report no. 15-909024-010

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[<0.0049% (w/w)] pH value and acidity of test item: stable	
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	The product is expected to be stable at 30°C for 9 weeks. Iodine content decrease >10% w/w after 18 weeks at 30°C; an appropriate label phrase is required to indicate that the biocidal product must not be stored at higher temperatures. Iodine content: ▫ T(0) = 0.294% (w/w) ▫ T(9 weeks) = 0.266% (w/w) (90.5% of T(0)) ▫ T(18 weeks) = 0.240% (w/w) (81.6% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.037% (w/w) ▫ T(9 weeks) = 0.066% (w/w) (178.4% of T(0)) ▫ T(18 weeks) = 0.092% (w/w) (248.6% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(9 weeks) = not detectable in test item	Demangel, B. (2015) Report no. 15-909024-015

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[<0.0049% (w/w)] ▫ T(18 weeks) = not detectable in test item [<0.0049% (w/w)] pH value and acidity of test item: stable	
		GERMICIDAN® IODES (Lot number: 15072801) 2.04% (w/w) Iodine	Product stable at 30°C for 20 weeks Iodine content: ▫ T(0) = 1.856% (w/w) ▫ T(9 weeks) = 1.766% (w/w) (95.15% of T(0)) ▫ T(20 weeks) = 1.722% (w/w) (92.79% of T(0)) pH value and acidity of test item: stable	Mayer, P. (2016) Report no. AT 09.02.01
Storage stability test – **long term storage at ambient temperature**	Technical Monograph No.17, 2nd Edition CropLife International	0.27 - 2.00 % (w/w) Iodine (all products)	Packaging: ANTI-GERM IO-SPRAY, ANTI-GERM IO-SPRAY-27, ANTI-GERM IO-BAR, ANTI-GERM IO-FILM-27, ANTI-GERM IO-BAR-27: Black opaque HDPE flasks, blue opaque HDPE flask and glass flask (4*10 L, 1*10 L and 500 mL respectively); GERMICIDAN® IODES: brown HDPE bottle of 1 L with screw top. a.s. content: For all tested products the sum of iodine content with iodide content is quite stable during storage, which means that the iodine	see below

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			seems to decompose in iodide. Further information: see below	
		ANTI-GERM IO-SPRAY (meta-SPC 1) (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 0.28% (w/w) ▫ T(6 months) = 0.26% (w/w) (92.9% of T(0)) ▫ T(12 months) = 0.25% (w/w) (89.3% of T(0)) ▫ T(18 months) = 0.24% (w/w) (85.7% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.03% (w/w) ▫ T(6 months) = 0.05% (w/w) (166.7% of T(0)) ▫ T(12 months) = 0.05% (w/w) (166.7% of T(0)) ▫ T(18 months) = 0.04% (w/w) (133.3% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(6 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(12 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 months) = not detectable in test item	Demangel, B. (2017), Report No. 15-909024-021

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			[<0.0049% (w/w)] <u>pH value (20°C, after 1 min):</u> ▫ T(0): 3.94 ▫ T(6 months): 3.80 ▫ T(12 months): 3.81 ▫ T(18 months): 3.66 <u>Acidity:</u> ▫ T(0): 0.083% w/w ▫ T(6 months): 0.088% w/w ▫ T(12 months): 0.095% w/w ▫ T(18 months): 0.11% w/w No relevant changes in the appearance (colour, odour, clarity), pH value and acidity after 18 months at 20°C (. Although the iodine content decrease is 14.3% w/w after 18 months at 20°C, based on the results of long term storage stability test (and the results of long term storage stability tests on the other four tested teat disinfection products) a shelf-life of 18 months is assumed. This is also further verified by the efficacy test with an aged product (18months) on“ANTI-GERM IO-FILM-27”. The available efficacy data (both P2S1 and	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			P2S2) demonstrate that ANTI-GERM IO-SPRAY is still fully efficacious at 80% product concentration. The shelf-life studies for ANTI-GERM IO-SPRAY demonstrate an iodine content of 85.7% of the initial value after a period of 18 months. In our view, the combination of both data permits granting a shelf-life of up to 18 months. (Please also refer to the conclusion below.)	
		ANTI-GERM IO-SPRAY-27 (meta-SPC 2) (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 0.27% (w/w) ▫ T(6 months) = 0.26% (w/w) (96.3% of T(0)) ▫ T(12 months) = 0.26% (w/w) (96.3% of T(0)) ▫ T(18 months) = 0.25% (w/w) (92.6% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.04% (w/w) ▫ T(6 months) = 0.05% (w/w) (125.0% of T(0)) ▫ T(12 months) = 0.06% (w/w) (150.0% of T(0)) ▫ T(18 months) = 0.05% (w/w) (125.0% of T(0)) <u>Iodate content:</u>	Demangel, B. (2017), Report No. 15-909024-028

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(6 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(12 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 months) = not detectable in test item [<0.0049% (w/w)] <u>pH value (20°C, after 1 min):</u> ▫ T(0): 3.88 ▫ T(6 months): 3.52 ▫ T(12 months): 3.50 ▫ T(18 months): 3.21 <u>Acidity:</u> ▫ T(0): 0.031% w/w ▫ T(6 months): 0.034% w/w ▫ T(12 months): 0.043% w/w ▫ T(18 months): 0.051% w/w No relevant changes in the active substance content, the appearance (colour, odour, clarity), pH value and acidity after 18 months at 20°C. Based on the results of long term storage stability test (and the results of long term storage stability tests on the other four	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			tested teat disinfection products) a shelf-life of 18 months is assumed.	
		ANTI-GERM IO-FILM (meta-SPC 3) (specified a.s. content: 0.27% (w/w) Iodine)	Product is very similar in composition to the 5 tested teat disinfection products. The long term storage characteristics at ambient temperature can be derived based on the results of the tested teat disinfection products. Based on the long term storage stability tests on the tested teat disinfection products a shelf-life of 18 months is assumed. The available efficacy data (both P2S1 and P2S2) demonstrate that the biocidal products of meta-SPC 3 are still fully efficacious at 80% product concentration. All shelf-life studies for products of the BPF demonstrate an iodine content of >80% of the initial value after a period of 18 months. In our view, the combination of both data permits granting a shelf-life of up to 18 months. (Please also refer to the conclusion below.)	Read-across to tested teat disinfection products
		ANTI-GERM IO-BAR (meta-SPC 3) (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 0.28% (w/w) ▫ T(6 months) = 0.28% (w/w) (100% of T(0)) ▫ T(12 months) = 0.26% (w/w) (92.9% of T(0))	Demangel, B. (2017), Report No. 15-909024-027

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(18 months) = 0.23% (w/w) (82.1% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.04% (w/w) ▫ T(6 months) = 0.04% (w/w) (100% of T(0)) ▫ T(12 months) = 0.04% (w/w) (100% of T(0)) ▫ T(18 months) = 0.07% (w/w) (175% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(6 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(12 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 months) = not detectable in test item [<0.0049% (w/w)] <u>pH value (20°C, after 1 min):</u> ▫ T(0): 4.13 ▫ T(6 months): 3.93 ▫ T(12 months): 3.86	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(18 months): 3.62 <u>Acidity:</u> ▫ T(0): not determined (pH value of test item > 4 and < 10 ▫ T(6 months): 0.13% w/w ▫ T(12 months): 0.19% w/w ▫ T(18 months): 0.25% w/w No relevant changes in the the appearance (colour, odour, clarity), pH value and acidity after 18 months at 20°C. Although the iodine content decrease is 17.9% w/w after 18 months at 20°C, based on the results of long term storage stability test (and the results of long term storage stability tests on the other four tested teat disinfection products) a shelf-life of 18 months is assumed. This is also further verified by the efficacy test with an aged product (18months) on“ANTI-GERM IO-FILM-27”. The available efficacy data (both P2S1 and P2S2) demonstrate that the biocidal products of meta-SPC 3 are still fully efficacious at 80% product concentration. All shelf-life studies for products of the BPF demonstrate an iodine content of >80% of	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the initial value after a period of 18 months. In our view, the combination of both data permits granting a shelf-life of up to 18 months. (Please also refer to the conclusion below.)	
		ANTI-GERM IO-FILM-27 (meta-SPC 4) (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 0.28% (w/w) ▫ T(6 months) = 0.25% (w/w) (89.3% of T(0)) ▫ T(12 months) = 0.24% (w/w) (85.7% of T(0)) ▫ T(18 months) = 0.23% (w/w) (82.1% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.04% (w/w) ▫ T(6 months) = 0.06% (w/w) (150.0% of T(0)) ▫ T(12 months) = 0.074% (w/w) (175.0% of T(0)) ▫ T(18 months) = 0.08% (w/w) (200.0% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(6 months) = not detectable in test item [<0.0049% (w/w)]	Demangel, B. (2017), Report No. 15-909024-029

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(12 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 months) = not detectable in test item [<0.0049% (w/w)] <u>pH value (20°C, after 1 min):</u> ▫ T(0): 4.00 ▫ T(6 months): 3.65 ▫ T(12 months): 3.50 ▫ T(12 months): 3.01 <u>Acidity:</u> ▫ T(0): 0.043% w/w ▫ T(6 months): 0.062% w/w ▫ T(12 months): 0.074% w/w ▫ T(18 months): 0.082% w/w No relevant changes in appearance (colour, odour, clarity), pH value and acidity after 18 months at 20°C. Although the iodine content decrease is 17.9% w/w after 18 months at 20°C, based on the results of long term storage stability test (and the results of long term storage stability tests on the other four tested teat disinfection products) a shelf-life of 18 months is assumed. This is also further verified by the efficacy test with an aged	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			product (18months) on“ANTI-GERM IO-FILM-27”. The available efficacy data (both P2S1 and P2S2) demonstrate that both biocidal products of meta-SPC 4 are still fully efficacious at 80% product concentration. All shelf life studies for products of the BPF demonstrate an iodine content of >80% of the initial value after a period of 18 months. We think that the assessment of storage stability and efficacy data permits a shelf life of 18 months. (Please also refer to the conclusion below.)	
		ANTI-GERM IO-BAR-27 (meta-SPC 4) (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 0.29% (w/w) ▫ T(6 months) = 0.28% (w/w) (96.6% of T(0)) ▫ T(12 months) = 0.26% (w/w) (89.7% of T(0)) ▫ T(18 months) = 0.25% (w/w) (86.2% of T(0)) <u>Iodide content:</u> ▫ T(0) = 0.04% (w/w) ▫ T(6 months) = 0.05% (w/w) (125.0% of T(0)) ▫ T(12 months) = 0.06% (w/w) (150.0% of T(0))	Demangel, B. (2017), Report No. 15-909024-030

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(18 months) = 0.05% (w/w) (125.0% of T(0)) <u>Iodate content:</u> ▫ T(0) = not detectable in test item [<0.0049% (w/w)] ▫ T(6 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(12 months) = not detectable in test item [<0.0049% (w/w)] ▫ T(18 months) = not detectable in test item [<0.0049% (w/w)] <u>pH value (20°C, after 1 min):</u> ▫ T(0): 3.91 ▫ T(6 months): 3.63 ▫ T(12 months): 3.35 ▫ T(18 months): 2.80 <u>Acidity:</u> ▫ T(0): 0.093% w/w ▫ T(6 months): 0.14% w/w ▫ T(12 months): 0.23% w/w ▫ T(18 months): 0.40% w/w No relevant changes in appearance (colour, odour, clarity), pH value and acidity after 18 months at 20°C.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Although the iodine content decrease is 13.8% w/w after 18 months at 20°C, based on the results of long term storage stability test (and the results of long term storage stability tests on the other four tested teat disinfection products) a shelf-life of 18 months is assumed. This is also further verified by the efficacy test with an aged product (18months) on“ANTI-GERM IO-FILM-27”. The available efficacy data (both P2S1 and P2S2) demonstrate that both biocidal products of meta-SPC 4 are still fully efficacious at 80% product concentration. All shelf life studies for products of the BPF demonstrate an iodine content of >80% of the initial value after a period of 18 months. We think that both the assessment of storage stability and efficacy data as well as the assessment of ANTI-GERM IO-FILM-27 permit a shelf life of 18 months. (Please also refer to the conclusion below.)	
		GERMICIDAN® IODES (Lot number: 15072801) 1.856% (w/w) Iodine	<u>Iodine content:</u> ▫ T(0) = 1.856% (w/w) T(3 months) = 1.778% (w/w) (95.8% of T(0)) ▫ T(6 months) = 1.751% (w/w) (94.3% of T(0))	Lehmann, R.. (2017) Report no. AT 09.02.01 (Intermediate Report after 18 months of storage)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(12 months) = 1.686% (w/w) (90.8% of T(0)) ▫ T(18 months) = 1.676% (w/w) (90.3% of T(0)) <u>pH value (20°C, after 1 min):</u> ▫ T(0): 2.11 ▫ T(3 months): 1.70 ▫ T(6 months): 1.87 ▫ T(12 months): 2.23 ▫ T(18 months): 2.11 <u>Acidity:</u> ▫ T(0): 10.10% w/w ▫ T(3 months): 10.29% w/w ▫ T(6 months): 10.10% w/w ▫ T(12 months): 10.10% w/w ▫ T(18 months): 10.13% w/w No relevant changes in active substance content, appearance (colour, odour, clarity), pH value, acidity and dilution stability after 18 months at 20°C. No relevant changes in persistent foaming after 36 months at 20°C. Based on the results of long term storage stability test a shelf-life of 18 months is assumed. (Please also refer to the conclusion below.)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	0.27 - 2.00 % (w/w) Iodine (all products)	Stable at 0 ± 2 °C for at least 7 days.	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	<u>Appearance (colour, odour, clarity):</u> ▫ T(0): Homogeneous dark brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous dark brown opaque liquid with a typical iodine odour <u>pH value (20°C, after 1 min):</u> ▫ T(0): 3.94 ▫ T(7 d): 3.92 <u>pH value (20°C, after 2 min):</u> ▫ T(0): 3.93 ▫ T(7 d): 3.91 <u>Acidity:</u> ▫ T(0): 0.082% w/w ▫ T(7 d): 0.082% w/w Stable at 0 ± 2 °C for 7 days.	Demangel, B. (2015) Report no. 15-909024-017
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	<u>Appearance (colour, odour, clarity):</u> ▫ T(0): Homogeneous brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous brown opaque liquid with a typical iodine odour <u>pH value (20°C, after 1 min):</u> ▫ T(0): 3.88	Demangel, B. (2015) Report no. 15-909024-002

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			▫ T(7 d): 3.90 <u>pH value (20°C, after 2 min):</u> ▫ T(0): 3.88 ▫ T(7 d): 3.90 <u>Acidity:</u> ▫ T(0): 0.031% w/w ▫ T(7 d): 0.034% w/w Stable at 0 ± 2 °C for 7 days.	
		ANTI-GERM IO-FILM (specified a.s. content: 0.27% (w/w) Iodine)	Read-across: Product is very similar in composition to the 5 tested teat disinfection products. Product is expected to be stable at 0 °C for 7 days	Read-across to tested teat disinfection products
		ANTI-GERM IO-BAR (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine)	<u>Appearance (colour, odour, clarity):</u> ▫ T(0): Homogeneous brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous brown opaque liquid with a typical iodine odour <u>pH value (20°C, after 1 min):</u> ▫ T(0): 4.13 ▫ T(7 d): 4.16 <u>pH value (20°C, after 2 min):</u> ▫ T(0): 4.12 ▫ T(7 d): 4.14	Demangel, B. (2015) Report no. 15-909024-023

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Stable at 0 ± 2 °C for 7 days.	
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	Appearance (colour, odour, clarity): ▫ T(0): Homogeneous brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous brown opaque liquid with a typical iodine odour pH value (20°C, after 1 min): ▫ T(0): 4.00 ▫ T(7 d): 4.12 pH value (20°C, after 2 min): ▫ T(0): 3.99 ▫ T(7 d): 4.09 Stable at 0 ± 2 °C for 7 days.	Demangel, B. (2015) Report no. 15-909024-007
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	Appearance (colour, odour, clarity): ▫ T(0): Homogeneous brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous brown opaque liquid with a typical iodine odour pH value (20°C, after 1 min): ▫ T(0): 3.91 ▫ T(7 d): 3.86 pH value (20°C, after 2 min): ▫ T(0): 3.89 ▫ T(7 d): 3.84	Demangel, B. (2015) Report no. 15-909024-002

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Acidity: ▫ T(0): 0.093% w/w ▫ T(7 d): 0.084% w/w Stable at 0 ± 2 °C for 7 days.	
		GERMICIDAN® IODES (Lot number: 15072801) 2.04% (w/w) Iodine	Appearance (colour, odour, clarity): ▫ T(0): Homogeneous brown opaque liquid with a typical iodine odour ▫ T(7 d): Homogeneous brown opaque liquid with a typical iodine odour pH value (1% solution, 20°C, after 1 min): ▫ T(0): 2.11 ▫ T(7 d): 2.03 pH value (1% solution, 20°C, after 2 min): ▫ T(0): 2.08 ▫ T(7 d): 2.01 Stable at 0 ± 2 °C for 14 days	Mayer, P (2016) Report no. AT 09.02.02
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	0.27 - 2.00 % (w/w) Iodine (all products)	Opaque packaging, therefore no impact on content of active substance due to exposure to light expected.	Waiving[6]
Effects on content of the active substance and technical characteristics	CIPAC MT 46.3	0.27 - 2.00 % (w/w) Iodine (all products)	*Temperature:* The effect of temperature on the content of the active substance is reported in the accelerated storage reports	Please see reference of the accelerated storage tests for each individual product ("Storage stability

[6] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
of the biocidal product – **temperature and humidity**			(storage at 30 °C); see above.	test – **accelerated storage**").
	-	0.27 - 2.00 % (w/w) Iodine (all products)	*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.	Waiving6
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The data about the packaging is sufficient.	Dangerous Goods Database http://www.dgg.bam.de/en/
Wettability	-	0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Suspensibility, spontaneity and dispersion stability	-	0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Wet sieve analysis and dry sieve test	-	0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Emulsifiability, re-emulsifiability and emulsion stability	-	0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Disintegration time	-	0.27 - 2.00 % (w/w) Iodine	Waiving according to "Guidance on the	Waiving[6]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(all products)	BPR, Volume I, Part A"	
Particle size distribution, content of dust/fines, attrition, friability	-	0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A" (Although ANTI-GERM IO-SPRAY, ANTI-GERM IO-SPRAY-27, GERMICIDAN® IODES and ANTI-GERM IODACID can be used for spray applications, the products are not sold in or together with spraying equipment. In particular, they are not sold as aerosol cans. ANTI-GERM IO-FILM, ANTI-GERM IO-BAR, ANTI-GERM IO-FILM-27 and ANTI-GERM IO-BAR-27 are not intended to be used for spray applications at all.)	Waiving[6]
Persistent foaming	-	ANTI-GERM IO-SPRAY	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
		ANTI-GERM IO-SPRAY-27		
		ANTI-GERM IO-FILM		
		ANTI-GERM IO-BAR		
		ANTI-GERM IO-FILM-27		
		ANTI-GERM IO-BAR-27		
	CIPAC MT 47.2	GERMICIDAN® IODES (Lot number: 15111901) 2.02 % (w/w) Iodine	No persistent foam formation under the experimental conditions used.	Mayer, P. (2016) Report no. AT 09.02.05
Flowability/Pourability/Dustability		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Burning rate — smoke generators		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Burning completeness — smoke generators		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Spraying pattern — aerosols		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
Physical compatibility		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A" (The products are not intended to be used with other products.)	Waiving[6]
Chemical compatibility		0.27 - 2.00 % (w/w) Iodine (all products)	Waiving according to "Guidance on the BPR, Volume I, Part A" (The products are not intended to be used with other products.)	Waiving[6]
Degree of dissolution and dilution stability	-	ANTI-GERM IO-SPRAY	Waiving according to "Guidance on the BPR, Volume I, Part A"	Waiving[6]
		ANTI-GERM IO-SPRAY-27		
		ANTI-GERM IO-FILM		
		ANTI-GERM IO-BAR		
		ANTI-GERM IO-FILM-27		
		ANTI-GERM IO-BAR-27		
	CIPAC MT 41.1	GERMICIDAN® IODES (Lot number: 15072801) 2.04% (w/w) Iodine	No separation after 30 min and 24 hours.	Mayer, P. (2016) Report no. AT 09.02.01
Surface tension	EU Method A.5 OECD Guideline 115	0.27 - 2.00 % (w/w) Iodine (all products)	ca. 25 – 33 mN/m (T = 20.0°C)	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	32.5 ± 0.1 mN/m (T = 20.0°C)	Demangel, B. (2015) Report no. 15-909024-016
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-	27.9 ± 0.1 mN/m (T = 20.0°C)	Demangel, B. (2015) Report no. 15-909024-001

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		28/01/2015) 0.271% (w/w) Iodine		
		ANTI-GERM IO-FILM (specified a.s. content: 0.27% (w/w) Iodine)	Read-across: Product is very similar in composition to the 5 tested teat disinfection products. A surface tension between 25-33 mN/m is expected.	Read-across to tested teat-disinfection products
		ANTI-GERM IO-BAR (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine)	29.1 ± 0.5 mN/m (T = 20.1°C)	Demangel, B. (2015) Report no. 15-909024-022
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	26.5 ± 0.7 mN/m (T = 19.7°C)	Demangel, B. (2015) Report no. 15-909024-006
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	25.2 ± 0.4 mN/m (T = 20.1°C)	Demangel, B. (2015) Report no. 15-909024-011
		GERMICIDAN® IODES (Lot number: 15111901) 2.02 % (w/w) Iodine	29.76 ± 0.07 mN/m (T = 20.3°C)	Mayer, P. (2016) Report no. AT 09.02.05
Viscosity	ISO Standard 3219 OECD Guideline 114	0.27 - 2.00 % (w/w) Iodine (all products)	see below	see below
		ANTI-GERM IO-SPRAY (Batch IO-SPRAY-20/02/2015) 0.278% (w/w) Iodine	2.96 mPa s (T = 20.0°C) 1.72 mPa s (T = 40.0 ± 0.2°C)	Demangel, B. (2015) Report no. 15-909024-016
		ANTI-GERM IO-SPRAY-27 (Batch IO-SPRAY-27-28/01/2015) 0.271% (w/w) Iodine	3.63 mPa s (T=20°C) 2.76 mPa s (T=40°C)	Demangel, B. (2015) Report no. 15-909024-001
		ANTI-GERM IO-FILM	Read-across: Product is very similar in	Read-across to ANTI-GERM IO-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(specified a.s. content: 0.27% (w/w) Iodine)	composition to IO-FILM-27. A dynamic viscosity of about 220 mPa s (50 s^{-1}) – about 12446 mPa s (0.25 s^{-1}) at T=20°C & about 200 mPa s (50 s^{-1}) – about 5155 mPa s (0.50 s^{-1}) at T=40°C is expected.	FILM-27
		ANTI-GERM IO-BAR (Batch IO-BAR-23/02/2015) 0.281% (w/w) Iodine	410 mPa s (50 s^{-1}) – 21652 mPa s (0.25 s^{-1}) (T=20°C) 324 mPa s (50 s^{-1}) – 19590 mPa s (0.25 s^{-1}) (T=40°C)	Demangel, B. (2015) Report no. 15-909024-022
		ANTI-GERM IO-FILM-27 (Batch IO-FILM-27-26/01/2015) 0.275% (w/w) Iodine	220 mPa s (50 s^{-1}) – 12446 mPa s (0.25 s^{-1}) (T=20°C) 200 mPa s (50 s^{-1}) – 5155 mPa s (0.50 s^{-1}) (T=40°C)	Demangel, B. (2015) Report no. 15-909024-006
		ANTI-GERM IO-BAR-27 (Batch IO-BAR-27-27/01/2015) 0.294% (w/w) Iodine	418 mPa s (50 s^{-1}) – 22495 mPa s (0.25 s^{-1}) (T=20°C) 336 mPa s (50 s^{-1}) – 19027 mPa s (0.25 s^{-1}) (T=40°C)	Demangel, B. (2015) Report no. 15-909024-011
		GERMICIDAN® IODES (Lot number: 15111901) 2.02 % (w/w) Iodine	10.5 mPa s (10 s^{-1}) – 8.5 mPa s (40 s^{-1}) (T=20°C) 7.3 mPa s (10 s^{-1}) – 4.0 mPa s (40 s^{-1}) (T=40°C)	Mayer, P. (2016) Report no. AT 09.02.05

Table 2

Conclusion on the physical, chemical and technical properties
meta SPC 1: The data provided by the applicant for meta SPC 1 was acceptable. The representative tested product ANTI-GERM IO-SPRAY is a homogeneous dark brown opaque liquid with a typical iodine odour. Its density is about 1.02 at 20°C; the measured surface tension was

32.5±0.1 mN/m at 20°C. The pH value of meta SPC 1 is about 4 (at the time of production). The viscosity of ANTI-GERM IO-SPRAY was 2.96 mPa s at 20°C and 1.72 mPa s at 40°C. The stability of the meta SPC at accelerated temperatures is assessed to be limited; therefore, an appropriate label phrase is required to indicate that the corresponding products must not be stored at higher temperatures. The representative product ANTI-GERM IO-SPRAY is stable at 0 ± 2 °C for at least 7 days. The assigned shelf-life is 18 months.
meta SPC 2: The data provided by the applicant for meta SPC 2 was acceptable. The representative tested product ANTI-GERM IO-SPRAY-27 is a homogeneous brown opaque liquid with a typical iodine odour. Its density is about 1.02 at 20°C; the measured surface tension was 27.9±0.1 mN/m at 20°C. The pH value of meta SPC 2 is about 4 (at the time of production). The viscosity of ANTI-GERM IO-SPRAY-27 was 3.63 mPa s at 20°C and 2.76 mPa s at 40°C. The representative product is stable at 0 ± 2 °C for at least 7 days. The assigned shelf-life is 18 months.
meta SPC 3: The data provided by the applicant for meta SPC 3 was acceptable. The representative tested product ANTI-GERM IO-BAR is a homogeneous brown opaque liquid with a typical iodine odour. Its density is about 1.04 at 20°C; the measured surface tension was 29.1 ± 0.5 mN/m at 20°C. The pH value of meta SPC 3 is about 4 (at the time of production). The viscosity of ANTI-GERM IO-BAR was 410 mPa s (50 s^{-1}) up to 21652 mPa s (0.25 s^{-1}) at 20°C and 324 mPa s (50 s^{-1}) up to 19590 mPa s (0.25 s^{-1}) at 40°C. The stability of the meta SPC at accelerated temperatures is assessed to be limited; therefore, an appropriate label phrase is required to indicate that the corresponding products must not be stored at higher temperatures. The representative product ANTI-GERM IO-BAR is stable at 0 ± 2 °C for at least 7 days. The assigned shelf-life is 18 months.
meta SPC 4: The data provided by the applicant for meta SPC 4 was acceptable. The tested products are homogeneous brown opaque liquids with a typical iodine odour. Their density is about 1.02-1.04 at 20°C; the measured surface tension was about 25-27 mN/m at 20.0°C. The pH value of meta SPC 4 is about 4 (at the time of production). The viscosity of ANTI-GERM IO-FILM-27 was 220 mPa s (50 s-1) up to 12446 mPa s (0.25 s-1) at 20°C and 200 mPa s (50 s-1) up to 5155 mPa s (0.25 s-1) at 40°C; the viscosity of ANTI-GERM IO-BAR-27 was 418 mPa s (50 s-1) up to 22495 mPa s (0.25 s-1) at 20°C and 336 mPa s (50 s-1) up to 19027 mPa s (0.25 s-1) at 40°C. The

stability of meta SPC 4 at accelerated temperatures is assessed to be limited; therefore, an appropriate label phrase is required to indicate that the corresponding products must not be stored at higher temperatures. The representative products are stable at 0 ± 2 °C for at least 7 days. The assigned shelf-life of meta-SPC 4 is 18 months.
meta SPC 5: The data provided by the applicant for meta SPC 5 was acceptable. The representative tested product GERMICIDAN® IODES is a homogeneous brown opaque liquid with a typical iodine odour. The density is about 1.08 at 20°C; the measured surface tension was 29.76 ± 0.07 mN/m at 20°C. The pH value of meta SPC 5 is about 2 (at the time of production). The viscosity of GERMICIDAN® IODES was 10.5 mPa s (10 s-1) up to 8.5 mPa s (40 s-1) at 20°C and 7.3 mPa s (10 s-1) up to 4.0 mPa s (40 s-1) at 40°C. The representative product GERMICIDAN® IODES is stable at 0 ± 2 °C for at least 7 days. The shelf-life is 18 months.
Shelf-life (all products): For all products (respectively meta SPCs) efficacy is demonstrated for 80% of the nominal active substance concentration. Additionally, the efficacy test on the 18 months old product ANTI-GERM IO-FILM-27 (meta SPC 4) shows that the product is still efficacious and thereby demonstrates that degradation products of the a.s. do not negatively impact the efficacy. For meta SPC 2 and 4, using the same Iodine premixes, a shelf life of 18 months can be set based on the storage stability study itself (meta SPC 2) or in combination with the efficacy study on aged product (meta SPC 4). Meta SPCs 1, 3 and 5 are using the same Iodine premixes (but a different one in comparison to meta SPC 2 and 4). Regarding the different iodine premixes: the main difference is used solvent, but since the different solvents have a similar structure (please refer to the confidential Annex), the difference is negligible. For meta SPC 5, a shelf life of 18 months can be set based on the storage stability study. For meta SPC 1 and 3, based on the storage stability results only, the assigned shelf life would be lower. But based on the additional data (efficacy tests with 80% nominal concentration, efficacy test on 18 months old ANTI-GERM IO-FILM-27) and the aspect that Iodine decomposes to iodide (risk assessment is based on the total iodine content: no impact of the degradation products on the risk

assessment) a shelf-life of 18 months can be set for meta SPC 1 and 3 as well.

In conclusion, considering all the data available, a shelf life of 18 months can be set for all five meta SPCs.

3.3 Physical hazards and respective characteristics

Table 3: Physical hazards and respective characteristics of the BPF

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	study scientifically not necessary			Waiver: 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.	IUCLID[7]
Flammable gases	study scientifically unjustified			Waiver	IUCLID[7]
Flammable aerosols	study scientifically unjustified			Waiver: The study does not need to be conducted because all biocidal products of this BPF are liquids.	IUCLID[7]
Oxidising gases	study scientifically unjustified			Waiver	IUCLID[7]
Gases under pressure	study scientifically unjustified			Waiver	IUCLID[7]
Flammable liquids	DIN EN ISO 2719	GERMICIDAN® IODES (Batch no: 15072801) 20.406 ppm Iodine	Flash point: no flash point under the test conditions up to 120°C	Not classified based on GHS/CLP criteria Waiver: With a single exception of traces of methanol (ppm) as a component in one mixture the teat disinfection products do not contain any flammable substances. Due to the intrinsic properties of the individual	Schütz, S.; Flash Point: GERMICIDAN® IODES, Report No. ISP-NG-2015-1 (2015)

[7] Data waiving was acceptable (see justification(s)/annotation(s) in IUCLID dossier).

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
		0.27 - 2.00 % (w/w) Iodine (all other products)		components, the high water content and known experience, none of these formulations of the BPF is expected to be flammable.	
Flammable solids	study scientifically unjustified			Waiver	IUCLID7
Self-reactive substances and mixtures	study scientifically not necessary			Waiver: 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.	IUCLID7
Pyrophoric liquids	study scientifically not necessary			Waiver: All products of this BPF are water based formulations. None of the components of the formulations is classified to have pyrophoric properties. In addition known experience in handling of the formulation does not indicate pyrophoric properties in contact with water or air.	IUCLID7
Pyrophoric solids	study scientifically unjustified			Waiver	IUCLID7
Self-heating substances and mixtures	study scientifically unjustified			Waiver	IUCLID7
Substances and mixtures which in contact with water emit flammable gases	study scientifically not necessary			Waiver: 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.	IUCLID7
Oxidising liquids	study scientifically not			Waiver: None of the products contain components which are classified as oxidising liquid. Due to the intrinsic	IUCLID7

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
	necessary			properties of the individual components, the high water content and known experience, the oxidising properties of all formulations of the BPF are predicted negative.	
Oxidising solids	study scientifically unjustified			Waiver	IUCLID7
Organic peroxides	study scientifically not necessary			Waiver: The study does not need to be conducted because all biocidal products of this BPF do not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	IUCLID7
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4, UN test C.1	GERMICIDAN® IODES (Batch no: 16092201)	uniform corrosion : mass loss: up to 100% (aluminium 7075, Steel S235JRG)	GERMICIDAN® IODES is corrosive to metals, Category 1 based on GHS/CLP criteria .	Rodriguez, N.; Report No. AQ066-16 (2016)
	UN Test in Part III of the UN-MTC, 37.4, UN test C.1	ANTI-GERM IO-Spray-27 (Batch no: IO-Spray-27-23.01.17)	- no mass loss higher than 51.5% was observed on steel (1.0037) and aluminium (7075-T6) plates after 28 days (highest mass loss found for steel: 4.1%; highest mass loss found for aluminium: 2.3%). - no localised corrosion attack was observed on neither steel (1.0037) nor aluminium (7075-T6) plates after 28 days This result is considered transferrable to products	ANTI-GERM IO-SPRAY-27 is classified as “not corrosive to metals” based on GHS/CLP criteria	Krebs, F. (2017), Report No. 17012703N979

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
			in meta-SPCs 1, 2, 3 and 4.		
Auto-ignition temperature (liquids and gases)	study scientifically not necessary			Waiver: With a single exception of traces of methanol (ppm) as a component in one mixture the teat disinfection products do not contain any flammable substances. GERMICIDAN® IODES does not contain any flammable substances and the flashpoint is >120°C. 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.	IUCLID/
Relative self-ignition temperature for solids	study scientifically unjustified			Waiver	IUCLID/
Dust explosion hazard	study scientifically unjustified			Waiver	IUCLID/

Table 4

Conclusion on the physical hazards and respective characteristics
Acceptable study was provided for the flashpoint of the biocidal product 'GERMICIDAN® IODES. As stated in the study report, the biocidal product doesn't have a flashpoint up to 120°C. Due to composition of the other biocidal products a flash point can to be excluded up to the boiling point of water. Based on experience in production and handling it can be concluded that the BPF is not pyrophoric or

auto-flammable and does not evolve flammable gases in contact with water.
BPF is not considered to be explosive or to have oxidising properties.

Corrosive properties were tested for the biocidal products GERMICIDAN® IODES and GERM IO-SPAY-27. Based on the experimental data the biocidal product GERMICIDAN® IODES (Meta SPC 5) has to be classified as corrosive to metals in Category 1.
Based on negative corrosion test results for the biocidal product ANTI-GERM IO-SPRAY-27, which can be assigned to meta-SPCs 1, 2, 3 and 4, no classification is required.

3.4 Methods for detection and identification

Table 5

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Iodine in ANTI-GERM IO-SPRAY	Titration with sodium thiosulphate solution	-	*no data – complementary method validation*	Specificity was demonstrated. Additionally, no interference of the detection and quantification of iodine in the formulation was observed.	97.4% – 99.1% (n=2)	98.3% (n=2)	-	Not relevant; method for determination of active substance in the products.	Ricau, H. (2015) Report no. 15-909024-018
Iodine in ANTI-GERM IO-SPRAY-27	Titration with sodium thiosulphate solution	3.09 – 9.40 mg of iodine (50-150%) n=5	Linear within the range of 3.09 mg to 9.40 mg of iodine; r^2 = 0.9992	Specificity was demonstrated. Additionally, no interference of the detection and quantification of iodine in the different formulations was	99.1% – 99.8% (n=2)	99.5% (n=2)	0.60% (from determination of precision, n=5)	Not relevant; method for determination of active substance in the products.	Ricau, H. (2015) Report no. 15-909024-003

				observed.					
Iodine in ANTI-GERM IO-FILM	The titration of iodine with sodium thiosulphate is described in the European Pharmacopoeia (*Ph. Eur.*), and can, thus, be considered a robust and reliable analytical method. The titration method has been fully validated for the product ANTI-GERM IO-SPRAY-27, and complementary validations have been performed for the other 4 teat disinfection products having the same content of active substance and a very similar composition. Therefore, it can be expected that the titration method is valid (i.e. specific, linear, precise, accurate and reproducible) for the product ANTI-GERM IO-FILM as well.								
Iodine in ANTI-GERM IO-BAR	Titration with sodium thiosulphate solution	-	*no data – complementary method validation*	Specificity was demonstrated.	100.6% – 101.5% (n=2)	101.1% (n=2)	-	Not relevant; method for determination of active substance in the different products.	Ricau, H. (2015) Report no. 15-909024-024
Iodine in ANTI-GERM IO-FILM-27	Titration with sodium thiosulphate solution	-	*no data – complementary method validation*	Specificity was demonstrated.	98.3% – 99.0% (n=2)	98.6% (n=2)	-	Not relevant; method for determination of active substance in the different products.	Ricau, H. (2015) Report no. 15-909024-008
Iodine in ANTI-GERM IO-BAR-27	Titration with sodium thiosulphate solution	-	*no data – complementary method validation*	Specificity was demonstrated.	98.3% – 99.9% (n=2)	99.1% (n=2)	-	Not relevant; method for determination of active substance in the different products.	Ricau, H. (2015) Report no. 15-909024-013
Iodine in GERMICIDAN® IODES	Titration with sodium thiosulphate solution	1.0678 g of iodine (50 – 150% of the analytical range) n=5	Linear within the range of 358.5 mg to 1.0678 g of iodine (; r^2 = 0.9996	Specificity was demonstrated.	97.05% – 97.13% (n=3)	97.1% (n=3)	0.06%	Not relevant; method for determination of active substance in the different products.	Mayer, P. (2016) Report no. AT 09.02.04
SoCs in GERMICIDAN® IODES	Phosphoric acid, laureth-11 carboxylic acid, butyl diglycol as well as the ethoxylated alcohols (alcohols, C12-15-branched and linear, ethoxylated propoxylated) are considered to be chemically stable and, therefore, not to decrease or increase on the manufacture or storage. Therefore, analytical methods for determination of the content of these substances in the biocidal product GERMICIDAN IODES are considered not to be necessary.								Waiving

	According to chapter III, section 3.4.2 “Effects on content of the active substance and technical characteristics of the biocidal product” of the Guidance on the Biocidal Products Regulation, Volume I, Identity/physico-chemical properties/analytical methodology, Part A, Information Requirements (version 1.1, Nov. 2014), in cases where the substance of concern or relevant impurity cannot possibly increase on manufacture or storage of the biocidal product then they do not need to be included in the storage stability/shelf-life study.								
SoCs in meta SPC 2 and meta SPC 4	Isotridecanol, ethoxylated and 1-Decanol, ethoxylated (8 EO) were identified as SoCs in meta SPC 2 and 4. These two substances are considered to be chemically stable and, therefore, not to decrease or increase on the manufacture or storage. Therefore, analytical methods for determination of the content of these substances in the biocidal product GERMICIDAN IODES are considered not to be necessary. According to chapter III, section 3.4.2 “Effects on content of the active substance and technical characteristics of the biocidal product” of the Guidance on the Biocidal Products Regulation, Volume I, Identity/physico-chemical properties/analytical methodology, Part A, Information Requirements (version 1.1, Nov. 2014), in cases where the substance of concern or relevant impurity cannot possibly increase on manufacture or storage of the biocidal product then they do not need to be included in the storage stability/shelf-life study.								
Iodide and Iodate in ANTI-GERM IO-SPRAY-27	Iodide: HPLC-UV after conversion of iodine into iodide using sodium thiosulfate; iodide = total iodide – available iodine	Iodide: n.d.	Iodide: Linear within the range of 20.58 mg/L – 205.76 mg/L R^2 = 0.9997	Iodide: Specificity was demonstrated in test item. No interference from solvent blank, blank formulation and solubilizing agents of the iodophor.	Iodide: 100.7% – 101.2% (n=4)	Iodide: 101.0%% (n=4)	Iodide: n.d.	Iodide: n.d.	Ricau, H. (2015) Report no. 15-909024-004
	Iodate: HPLC-UV	Iodate: n.d.	Iodate: Linear within the range of 4.86 mg/L – 20.24 mg/L R^2 = 0.9988	Iodate: Specificity was demonstrated in test item. No interference from solvent blank, blank formulation and solubilizing agents of the iodophor.	Iodate: 98.6% - 100.1% (n=4)	Iodate: 99.4% (n=4)	Iodate: n.d.	Iodate: LOD = 0.015 g/kg (0.0015% w/w) LOQ = 0.049 g/kg (0.0049% w/w)	

Iodide and iodate in teat disinfection products	The HPLC-UV method for determination of iodide and iodate has been fully validated for the product ANTI-GERM IO-SPRAY-27 (Ricau, H. (2015), Report no. 15-909024-004), and complementary validations have been performed for the other 4 teat disinfection products having the same content of active substance and a very similar composition: ▫ Iodide and Iodate in ANTI-GERM IO-SPRAY: Ricau, H. (2015), Report no. 15-909024-019 ▫ Iodide and Iodate in ANTI-GERM IO-BAR: Ricau, H. (2015), Report no. 15-909024-025 ▫ Iodide and Iodate in ANTI-GERM IO-FILM-27: Ricau, H. (2015), Report no. 15-909024-009 ▫ Iodide and Iodate in ANTI-GERM IO-BAR-27: Ricau, H. (2015), Report no. 15-909024-014 Therefore, it can be expected that the HPLC-UV method is valid (i.e. specific, linear, precise, accurate and reproducible) for the product ANTI-GERM IO-FILM as well.
Iodide in GERMICIDAN® IODES	A quantitative method for the determination of iodide in the product GERMICIDAN® IODES could not be developed due to technical problems related to interference from iodine in the test item. Finally, the monitoring of iodine, iodide and iodate in the ANTI-GERM IO-products has shown that iodine is degraded to iodide during storage.

Table 6

Analytical methods for monitoring of active substances and residues in food of animal origin									
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		
iodide	HPLC-ECD, Partisphere C18 column	0.5 – 4.6 mg/kg (milk powder) 300 µg/L (liquid milk)	20-250 ng/mL	no data	75-106 %88 %	- -	9-13 % 8 %	Limit of determination: 0.03 mg/kg (whole milk) 0.3 mg/kg (milk	CAR, Doc IIIA, 4.3.1 ISO 14378 & Sertl et al. 1993

								powder)	

Table 7

Data waiving was acceptable for the following information requirements	
Information requirement	1. Analytical method including validation parameters for determining the concentration of the substances of concern in the biocidal product: According to chapter III, section 3.4.2 of the Guidance on the Biocidal Products Regulation, Volume I, Identity/physico-chemical properties/analytical methodology, Part A, Information Requirements (version 1.1, Nov. 2014), in cases where the SoC or relevant impurity cannot possibly increase on manufacture or storage of the biocidal product then they do not need to be included in the storage stability/shelf-life study. 2. Methods regarding residues in soil, drinking water and surface water, food of plant origin as well as body fluids and tissues were not necessary. 3. Analytical methods for the determination of active substance in air were not submitted for the BPF since this point is covered by the data set of the active substance iodine in the corresponding CAR. Due to the expected exposure levels (below 1% of the corresponding reference values) determined from local risk assessment for the SoCs orthophosphoric acid and (2-butoxyethoxy)ethanol (butyldiglycol) analytical methods for air for these SoCs are not considered to be essential for occupational safety. For the SoCs isotridecanol, ethoxylated and decan-1-ol, ethoxylated analytical methods for air are not required due to their low vapour pressure. Methods regarding residues in air for general public were not necessary because of professional use only.
Justification	See justification(s)/annotation(s) in IUCLID dossier

Table 8

Conclusion on the methods for detection and identification
The methods provided regarding the active substance in the biocidal products of the meta SPCs are acceptable. Methods regarding the SoCs were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

3.5.1.1 *meta SPCs 1-4*

Meta SPC 1-4 of the BPF comprise biocidal products based on the active substance iodine for the use as non-medical teat disinfectants in veterinary hygiene (PT 3). This includes six liquid ready-to-use products with an intended use concentration of 0.27% (2700 ppm) available iodine. The products are intended to be used after milking. They can be applied manually by dipping, foaming, spraying or by automated spraying by robot. The use is restricted for professionals only.

3.5.1.2 *meta SPC 5*

Meta SPC 5 of the BPF includes biocidal products based on the active substance iodine with alcohol ethoxylate surfactant in an acidic solution. The intended use is disinfection of clean non-porous surfaces in animal housing (PT 3). The concentrate has an active substance content of 2% available iodine and is diluted with water before application to yield use concentration of 1% product (0.02% available iodine) for bactericidal and yeasticidal action or 2% product (0.04% available iodine), for additional virucidal action, respectively. The products are intended to be used for disinfection of pre-cleaned surfaces and are applied by manual spraying. The use is restricted to professionals only.

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

3.5.2.1 *meta SPCs 1-4*

The biocidal products reduce the number of bacteria as well as yeasts that occur on the skin of teats of milk producing animals, e.g. dairy cows, buffaloes, sheep and goats. The products are applied in order to maintain a hygienic status of the teat skin and improved hygiene of raw milk, and thus to ensure animal and food safety. Humans are indirectly protected as consumers of milk and milk products.

3.5.2.2 *meta SPC 5*

The biocidal products are intended to control bacteria, yeast as well as viruses, which occur on clean non-porous surfaces in the veterinary area. The product is applied in order to increase hygiene in animal accommodations to improve animal health.

3.5.3 Effects on target organisms, including unacceptable suffering

3.5.3.1 *meta SPCs 1-4*

Applications of products within the meta SPCs 1-4 lead to the reduction in the number of target organisms by irreversible inactivation of bacterial and yeast cells (bactericidal and yeasticidal activity).

3.5.3.2 *meta SPC 5*

The applications of products within the meta SPC 5 leads to the reduction of target organisms by irreversible inactivation of bacterial and yeast cells as well as viruses (bactericidal, yeasticidal and virucidal activity).

3.5.4 Mode of action, including time delay

The mode of action of the active substance iodine is non-selective and 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 proteins 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 functional groups of proteins, in particular the free sulphur amino acids of cysteine and methionine, as well as 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 mode of action of iodine in particular the penetration into microorganisms indicate that the contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and on the concentration of iodine used in the treatment. Furthermore, iodine is more effective at higher temperatures.

3.5.5 Efficacy data

3.5.5.1 *meta SPCs 1-4*

Products are applied to disinfect the teats of milk producing animals, e.g. dairy cows, sheeps and goats after milking (recommended contact time at least five minutes with the undiluted product). The ready to use products in the meta SPCs 1-4 contain 0.27% (2700 ppm) available iodine as the biocidal active substance and various co-formulants which are not expected to have an impact on the efficacy.

Efficacy tests have been performed with all six products for the bactericidal function, but for the yeasticidal function a read-across (ANTI-GERM IO-FILM (meta SPC 3) with ANTI-GERM IO-SPRAY (meta SPC 1)) was justified by similar compositions.

To substantiate the claims for bactericidal and yeasticidal activity of products within the meta SPCs 1 - 4, efficacy studies have been performed according to European Standards (EN). As the products within the BPF are intended to be applied for teat disinfection, the formulations were tested in a tiered approach with a Phase 2, Step 1 test (quantitative suspension test) followed by a Phase 2, Step 2 test (quantitative carrier test on artificial skin). All studies were performed with obligatory test conditions (contact time: five minutes; temperature: 30°C) and under relevant soiling conditions (10 g/l skimmed milk).

Study results

The bactericidal and yeasticidal efficacy of the teat disinfectants was tested according to the 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 because no standard exists to test yeasticidal activity of teat disinfectants.

The laboratory studies were performed in a quantitative suspension test. Cell suspensions of representative strains of gram-positive and gram-negative bacteria (*Escherichia coli, Staphylococcus aureus and Streptococcus uberis*) as well as of yeast (*Candida albicans*) were diluted in a solution of interfering substance (10 g/l skimmed milk) and mixed with the biocidal product at the intended use concentration. After a contact time of five minutes (or in few tests additionally one minute) for post-milking application at 30°C test temperature, the biocidal action was immediately neutralised in a dilution-neutralisation procedure. A sample was subsequently incubated on Petri dishes with nutrient medium and the number of colony forming units was determined. In conclusion, the bactericidal activity of a product is defined according to the guideline EN 1656 as the capability to reduce the viability of the reference strains *Escherichia coli, Staphylococcus aureus and Streptococcus uberis* by a factor of minimum 10^5 or 5 lg (99.999%) under the conditions of the test; the yeasticidal activity of a product is defined according to the guideline EN 1657 as the capability to reduce the viability of the reference strain *Candida albicans* by a factor of minimum 10^4 or 4 lg (99.99% reduction).

For all products, efficacy after a 5 minutes contact time was demonstrated. The only exception was a read-across for the yeasticidal function after 5 minutes (ANTI-GERM IO-FILM (meta SPC 3) with ANTI-GERM IO-SPRAY (meta SPC 1)) which is justified due to comparable compositions.
1 minute contact time was only tested in the phase 2 step 1 tests (3 bactericidal and 1 yeasticidal function product tests). However, read-across was justified due to comparable compositions with “ANTI-GERM IO-SPRAY” which was tested for 1 min.

There is no European standard method for phase 2 step 2 quantitative surface tests available for testing the efficacy of post-milking teat disinfection in the veterinary area. Therefore, a modified EN 16437 test protocol has been established by the applicant to demonstrate bactericidal activity of the teat disinfectant products. The test temperature (30°C), contact time (5 minutes) and the soiling (10 g/l skimmed milk) have been adapted according to EN 1656 for teat disinfection. A standardized synthetic skin (Vitroskin) was employed as a carrier. In accordance with the decision of the EFF WG III 2016, surface tests were performed using only one test organism (*Staphylococcus aureus,* which was demonstrated to be the least susceptible test organism according to the suspension test EN 1656). A log reduction of 4 is required for post-milking disinfection phase 2 step 2 tests according to the EFF WG V 2015. The tests demonstrated that the iodine based BPF has a bactericidal activity in case of post-milking teat disinfection within 5 minutes contact time.

Additionally, the applicant submitted a phase 2 step 2 quantitative surface test with an 18 months old product. The study demonstrates that even after storage of 18 months at room temperature, the biocidal product Anti-Germ IO-Film-27 is efficacious against Staphylococcus aureus DSM 799.

An overview on study results is given in Table 9. Experimental data is summarised in Table 10.

Table 9

Study results on the efficacy of the biocidal products against target organism(s)								
European Standard	**Contact time [minutes]**	**Test ANTI_GERM IO-products**						
		Meta-SPC 1	**Meta-SPC 2**	**Meta-SPC 3**		**Meta-SPC 4**		
		IO-SPRAY	IO-SPRAY-27	IO-FILM	IO-BAR	IO-FILM-27	IO-BAR-27	
EN 1656	1 minute	X	R.-a.	X	X	R.-a.	R.-a.	bactericadal
	5 minutes	X	X	X	X	X	X	
phase 2 step 2	1 minute	n/a	n/a	n/a	n/a	n/a	n/a	
	5 minutes	X	X	X	X	X	X	
	5 minutes with an 18 months old product	n/a	n/a	n/a	n/a	X	n/a	
EN 1657	1 minute	X	R.-a.	R.-a.	R.-a.	R.-a.	R.-a.	yeasticidal
	5 minutes	X	X	R.-a.	X	X	X	
phase 2 step 2	1 minute	n/a	n/a	n/a	n/a	n/a	n/a	
	5 minutes	n/a	n/a	n/a	n/a	n/a	n/a	

X	Requirements of respective EN standard for bactericidal/yeasticidal activity have been met.
n/a	Results not available, study has not been submitted.
R.-a.	Read-across with IO-SPRAY.

Table 10

Use 1: teat disinfection meta SPC 1-4

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**
Phase 2, Step 1 Tests						
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-BAR-27 Meta-SPC 4	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk	The bactericidal concentration determined under

					Test temperature: 30°C Contact time: 5 min (1 min "read-across" EN1656 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥5 lg	obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-BAR-27 Meta-SPC 4	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min (1 min "read-across" EN1657 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-FILM-27 Meta-SPC 4	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min (1 min "read-across" EN1656 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-FILM-27 Meta-SPC 4	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after

					Contact time: 5 min (1 min “read-across” EN1657 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥4 lg	1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY-27 Meta-SPC 2	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min (1 min “read-across” EN1657 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY-27 Meta-SPC 2	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min (1 min “read-across” EN1657 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-BAR Meta-SPC 3	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 1 min, 5 min Test concentrations: 0.1%, 60%, 80%	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%.

					Reduction factor: ≥5 lg	The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-BAR Meta-SPC 3	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min (1 min "read-across" EN1657 ANTI-GERM IO-SPRAY) Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-FILM Meta-SPC 3	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 1 min, 5 min Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-FILM Meta-SPC 3	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	"read-across" ANTI-GERM IO-SPRAY	ANTI-GERM IO-FILM and IO-SPRAY are similar in composition with the same active substance content of 0.27% iodine. The presence of the thickener Xanthan Gum in IO-FILM is not expected to affect the efficacy. Therefore the

						results can be regarded to be similar. The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY Meta-SPC 1	*Escherichia coli, Staphylococcus aureus, Streptococcus uberis*	EN 1656	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 1 min, 5 min Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥5 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to EN 1656 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
PT3, biocidal product, yeasticidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY Meta-SPC 1	*Candida albicans*	EN 1657, modified by choosing additional test conditions as given in EN 1656 for teat disinfectants	Suspension test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 1 min, 5 min Test concentrations: 0.1%, 60%, 80% Reduction factor: ≥4 lg	The yeasticidal concentration determined under test conditions for teat disinfection according to EN 1657 after 1 minute and 5 minutes contact time is: 60% and 80%. The results comply with the requirements for post-milking application.
Phase 2, Step 2 Tests						
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-BAR Meta-SPC 3	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 5%, 80%, 100%	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 1 minute and 5 minutes contact time is:

					(w/v) Reduction factor: ≥4 lg	80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM *IO-BAR-27* Meta-SPC 4	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 5 minutes contact time is: 5%, 80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM *IO-FILM* Meta-SPC 3	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 5 minutes contact time is: 80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-FILM-27 Meta-SPC 4	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 5 minutes

					concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	contact time is: 80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY Meta-SPC 1	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 5 minutes contact time is: 80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity	teat disinfection, post-milking	ANTI-GERM IO-SPRAY-27 Meta-SPC 2	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test organisms.	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min Test concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437 after 5 minutes contact time is: 80% and 100% (w/v). The results comply with the requirements for post-milking application.
PT3, biocidal product, bactericidal activity after 18 months storage	teat disinfection, post-milking	ANTI-GERM IO-FILM-27-after 18 months storage Meta-SPC 4	*Staphylococcus aureus*	Modified EN 16437 by choosing the test conditions as given in EN 1656 for teat disinfectants and only one of the four mandatory test	Surface test Interfering substance: 1% skimmed milk Test temperature: 30°C Contact time: 5 min	The bactericidal concentration determined under obligatory test conditions for teat disinfection according to the modified EN 16437

				organisms.	Test concentrations: 5%, 80%, 100% (w/v) Reduction factor: ≥4 lg	after 5 minutes contact time is: 5%, 80% and 100% (w/v). The results comply with the requirements for post-milking application.

3.5.5.2 *meta SPC 5*

To substantiate the claims for bactericidal, yeasticidal and virucidal activity of products within meta SPC 5, efficacy studies have been performed according to European Standards (EN). As the products are intended to be applied for surface disinfection, the formulations were tested in a tiered approach with a phase 2, step 1 test (quantitative suspension test) followed by a phase 2, step 2 test (quantitative surface test). All studies were performed under clean conditions (3.0 g/l bovine serum albumin as interference substance) with a contact time of 30-60 min and the temperature of 10°C. The products were tested in three product concentrations: 0.01%, 1.0% and 2.0%.
The choice of use dilution was based on the practical application of the products. The instructions for use clearly indicate that the products are for use after thorough cleaning. Therefore, the efficacy tests were performed with low level soiling.
Veterinary hard surface biocidal products should be at least sufficiently effective against bacteria and yeasts. Additionally, products can claim a virucidal activity if efficacy against non-enveloped viruses has been proven according to EN 14675. So far, no standardized methods for phase 2 step 2 quantitative surface tests with viruses are established. Therefore, the claimed virucidal activity of a biocidal product used for hard surface disinfection is based on a quantitative suspension test (EN 14675).

Study results
The bactericidal and yeasticidal efficacy of the surface disinfectants was tested according to the standard EN tests for phase 2 step 1 (EN 1656 and EN 1657) as well as phase 2 step 2 (EN 14349 and EN 16438). The phase 2 step 2 standard EN 16438 for demonstration of yeasticidal activity, was only tested for 60 minutes contact time (as recommended according to the EN test guideline).
The virucidal efficacy of GERMICIDAN IODES was investigated in a suspension test according to EN 14675 under simulated use conditions for surface disinfection in the veterinary area. The bovine enterovirus type 1 (*Entero Cytopathogenic Bovine Orphan* ECBO) virus was selected as the model virus for the large genus Picornavirus. The mandatory quantitative suspensions test (phase 2 step 1) did not demonstrate a sufficient efficacy for 60 min and 1%. However, a contact time of 60 minutes at a product concentration of 2% was demonstrated to be efficacious.

A detailed overview on study results is given in Table 11. All studies were submitted as key studies. Experimental data is summarised in Table 12.

Table 11

Study results on the efficacy of the biocidal product against target organism(s)				
European Standard	**Contact time**	**Dilution**	**Biocidal product**	**Activity**
EN 1656	30 minutes	*0.01%*	*N*	bactericidal
		1%	*X*	
		2%	*X*	
EN 14349	30 minutes	*0.01%*	*N*	
		1%	*X*	
		2%	*X*	
EN 1657	30 minutes	*0.01%*	*N*	yeasticidal

		1%	*X*	
		2%	*X*	
EN 16438	60 minutes	*0.01%*	*N*	
		1%	*X*	
		2%	*X*	
EN 14675	30 minutes	*0.01%*	*N*	virucidal
		1%	*N*	
		2%	*N*	
EN 14675	60 minutes	*0.01%*	*N*	
		1%	*N*	
		2%	*X*	

X	Requirements of respective EN standard tests have been met.
N	Requirements of respective EN standard have NOT been met.

Table 12

Use 2: surface disinfection meta SPC 5

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**
Phase 2, Step 1 Tests							
PT3, biocidal product, bactericidal activity	Surface disinfection in the veterinary area	GERMICIDANIODES	*Enterococcus hirae, Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus*	EN 1656	Quantitative suspension test Interfering substance: 3.0 g/l bovine serum albumin (low level soiling conditions) Test temperature: 10°C Contact time: 30 minutes Test concentrations: 0.01, 1.0, 2.0% Reduction factor: ≥5 lg	The bactericidal activity determined under obligatory test conditions according to EN 1656 was reduced by a factor of ≥5 lg (99.999%) at a concentration of 1%. The results comply with the requirements for surface disinfection in the veterinary area.	*Brill, F. (2015):* Germicidan Iodes, *EN1656,* L15/0421.1
PT3, biocidal product, yeasticidal activity	Surface disinfection in the veterinary area	GERMICIDANIODES	*Candida albicans*	EN 1657	Quantitative suspension test Interfering substance: 3.0 g/l bovine serum albumin (low level soiling conditions)	The yeasticidal activity determined under obligatory test conditions according to EN 1657 was reduced by a factor of ≥4 lg	*Brill, F. (2015):* Germicidan Iodes, *EN1657,* L15/0421.10

					Test temperature: 10°C Contact time: 30 minutes Test concentrations: 0.01, 1.0, 2.0% Reduction factor: ≥4 lg	(99.99%) at a concentration of 1%. The results comply with the requirements for surface disinfection in the veterinary area.	
PT3, biocidal product, virucidal activity	Surface disinfection in the veterinary area	GERMICIDANIODES	Bovine enterovirus-1 (ECBO) virus	EN 14675 test conditions adapted for veterinary area	Quantitative suspension test Interfering substance: 3.0 g/l bovine serum albumin (low level soiling conditions) Test temperature: 10°C Contact time: 30 minutes Test concentrations: 0.01, 1.0, 2.0% Reduction factor: ≥4 lg	The virucidal activity determined under obligatory test conditions for surface disinfection according to EN 14675 was reduced by a factor of ≥4 lg (99.99%) at a concentration of 2% after 60 minutes contact time. The results do comply with the requirements for hard surface disinfection in the veterinary area.	*Brill, F., Steinmann, J. (2015):* Germicidan Iodes, *EN14675,* A15L0414bE
Phase 2, Step 2 Tests							
PT3, biocidal product, bactericidal activity	Surface disinfection in the veterinary area	GERMICIDANIODES	*Enterococcus hirae, Proteus vulgaris, Pseudomonas aeruginosa, Staphylococcus aureus*	EN 14349	Quantitative non-porous surface test Interfering substance: 3.0 g/l bovine serum albumin (low level soiling conditions) Test temperature: 10°C Contact time: 30 minutes Test concentrations: 0.01, 1.0, 2.0% Reduction factor: ≥4 lg	The bactericidal activity determined under obligatory test conditions for hard surface disinfection according to EN 14349 was reduced by a factor of ≥4 lg (99.99%) at a concentration of 1%. The results comply with the requirements for hard surface disinfection in the veterinary area.	*Brill, F. (2015):* Germicidan Iodes, *EN14349,* L15/0421.4
PT3, biocidal product, yeasticidal activity	Surface disinfection in the veterinary area	GERMICIDANIODES	*Candida albicans*	EN 16438	Quantitative non-porous surface test Interfering	The yeasticidal activity determined under obligatory test	*Brill, F. (2015):* Germicidan Iodes, *EN16438,*

					substance: 3.0 g/l bovine serum albumin (low level soiling conditions) Test temperature: 10°C Contact time: 60 minutes Test concentrations: 0.01, 1.0, 2.0% Reduction factor: ≥3 lg	conditions for hard surface disinfection according to EN 16438 was reduced by a factor of ≥3 lg (99.9%) at a concentration of 1%. The results comply with the requirements for hard surface disinfection in the veterinary area.	L15/0421. 11

3.5.6 Occurrence of resistance and resistance management

Taking into account the mode of action of iodine, which is non-selective, development of resistance against iodine is unlikely. Iodine / iodophors have been used for over 170 years as disinfectants for a variety of applications. Such applications include disinfection of skin in the human hygiene and medical area but also skin of animals using teat dips as well as surfaces such as milk tanks. No reduction in efficacy was reported to the producers of iodine/iodophor-based products for such applications indicating that no development of resistant microorganisms or viruses has occurred.

No management strategies have been developed since no occurrence of resistance has been observed.

3.5.7 Known limitations

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of the BPF.

3.5.8 Evaluation of the label claims

3.5.8.1 *meta SPCs 1-4*

The labels of the BPF 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 1 minute is recommended in order to ensure sufficient time for the bactericidal and yeasticidal activity (see Table 13). However, the efficacy has only been demonstrated after 5 minutes in the phase 2 step 2 tests.

Thus, it cannot be concluded that a sufficient efficacy is ensured by following the use instructions on the labels.

Table 13

Claim	Evaluation/Remark
ANTI-GERM® IO-"Product" is efficient without dilution with a contact time of one minute against bacteria and yeast, according EN1656 and EN1657	For all products the efficacy after a five minutes contact time was demonstrated. Therefore the claim on demonstrated efficacy with a contact time of one minute is inconsistent with the provided data.

3.5.8.2 *meta SPC 5*

The label of the product GERMICIDAN IODES intends to provide the use instructions as detailed in Table 14.
The dilution, in-use concentration as well as the contact time needed for the respective use is provided on the label in order to ensure sufficient time for the bactericidal, yeasticidal and virucidal activity. The label claims a 1-2 % dilution and a contact time of 30 minutes (see Table 14), whereas only a dilution of 2 % and a contact time of 60 minutes has been demonstrated as efficient in the submitted virucidal activity study. Furthermore, the submitted phase 2 step 2 test yeasticidal activity only showed a 60 minutes contact time.
Thus, it cannot be concluded that a sufficient efficacy is ensured by following the use instructions on the label.

Table 14

Claim	Evaluation/Remark
"Apply GERMICIDAN® IODES on previously cleaned surfaces".	The submitted tests were performed under clean conditions which is consistent with previously cleaned surfaces.
"Apply GERMICIDAN® IODES by using a spraying device, at ambient temperature, at a concentration of **1-2%,** in solution in water. The surfaces should be thoroughly wetted. The application rate should be ca. 400 mL/m²".	The efficacy has to be demonstrated for the lowest dose in the concentration range. In this case 1%. However, for viruses efficacy was only demonstrated according to EN 14675 after 60 min at a concentration of 2%. Therefore, the label claim for the concentration has not been demonstrated by efficacy data.
"After application, leave the surfaces to dry (for **porous surfaces**, leave to dry at least during 4 hours). The contact time should be at least **30 minutes** (60 minutes for an efficacy against **spores**, or in the case of use on **porous surfaces)".**	No test has been submitted for the demonstration of efficacy on porous surfaces. EN 16437,a phase 2 step 2 porous surface test for bactericide has not been submitted. Thus, the efficacy on porous surfaces is not proven. According to EN 16438 and EN 1657, spores are only included in the demonstration of efficacy if the additional reference organism *Aspergillus brasiliensis* ATCC 16404 is included in the testing. However, in this case only *Candida Albicans* was tested. Therefore, the efficacy of the products was only demonstrated for the yeasticidal activity and the efficacy against spores is not proven.

"GERMICIDAN® IODES is efficient against bacteria, fungi and **viruses** at a concentration of 1% according to EN1656, EN14349, EN1657, EN16438 and **EN14675**, with a contact time of 30 minutes. GERMICIDAN® IODES is efficient against bacteria, on **porous surfaces**, at a concentration of 1%, according to **EN16437, with a contact time of 60 minutes**. According to **EN13704, GERMICIDAN® IODES is efficient against spores at a concentration of 1%, with a contact time of 60 minutes".**	As described earlier, the claim on fungicidal activity is not proven. Only the claim on yeasticidal activity has been demonstrated via EN 1656 and EN 16438 tests with *Candida Albicans*. The claim on efficacy against spores according to EN 13704 is not proven because no test has been submitted. The demonstration of efficacy against viruses according to the pass requirement of EN 14675 was not successful for a contact time of 30 minutes at the concentration of 1%. The claim on virucidal activity was only proven for a 60 minutes contact time at a concentration of 2%. The phase 2 step 2 test for the demonstration of yeasticidal efficacy was submitted with a 60 minutes contact time. As mentioned above, no test for the demonstration of efficacy on porous surfaces has been submitted. Therefore the claim according to EN 16437 is not proven.

3.5.9 Data waiving and conclusion

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	No data waiving.

Table 16

Conclusion on the efficacy
meta SPCs 1-4 It can be concluded that the six ready-to-use products of the "Anti-germ iodine based disinfectants product family" show sufficient bactericidal and yeasticidal activity as substantiated according to European Standards (EN). The results showed a bactericidal and yeasticidal efficacy according to the international standards EN 1656, EN 1657 and a modified EN 16437 test under the defined test conditions. The results comply with the requirements for post-milking applications after 5 minutes contact time. There are no known limitations to the efficacy against target organisms. Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of meta SPCs 1-4 have been met. **meta SPC 5** The tested product, GERMICIDAN IODES is intended to be used for disinfection of clean non-porous surfaces and is applied by manual spraying. It can be concluded that the product GERMICIDAN IODES shows sufficient bactericidal, yeasticidal and virucidal activity as substantiated according to European Standards (EN). The results showed a bactericidal, yeasticidal and virucidal efficacy according to the international standards EN 1656, EN 1657, EN 14349, EN 16438 and EN 14675. The bactericidal activity was demonstrated for a 30 min contact time at a concentration of 1%. The 60 min contact time for the yeasticidal efficacy was

demonstrated at a product concentration of 1%. The virucidal activity was proven for a 2% concentration after a 60 min contact time.

There are no known limitations to the efficacy against target organisms. Resistance is not reported or known at the time being. Hence, with regard to efficacy, the requirements for the authorisation of meta SPC 5 have been met for a product concentration of 2%.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of active substance on Human Health

The toxicology of the active substance was examined extensively according to standard requirements for the purpose of inclusion in the positive list of Regulation 528/2012. The results of these toxicological assessments can be found in the respective CAR, a summary is provided in the Assessment Report (RMS SE, 13 December 2013). Threshold limit values and other relevant information are summarised in the tables below. Additional information on the toxicology of the active substance was not provided.

Table 17 Reference Values for the Active Substance Iod

	Value	Source
AEL (long-term, medium-term, acute) = Upper Intake Level (UL)	Europe 600 µg/d (0.01 mg/kg bw/d)	Assessment-Report (RMS SE (13 December 2013))
AEC Inhalative	0.1 ppm (1 mg/m^3)	Assessment-Report (RMS SE (13 December 2013))
ADI	0.01 mg iodine/kg	Assessment-Report (RMS SE (13 December 2013))
Oral absorption	> 90 %	Assessment-Report (RMS SE (13 December 2013))
Dermal absorption	11.3 – 12 %	Assessment-Report (RMS SE (13 December 2013))
	75 %	Default value for untested products/formulations with a.s. concentration < 5 % (EFSA Journal 2012;10(4):2665)

Table 18 Classification and other toxicological information for the Active Substance Iodine

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	Warning; Acute Tox 4, H332 Harmful if inhaled Acute Tox 4, H312 Harmful in contact with skin
Proposed, with regard to toxicological data according to the criteria in Reg. 1272/2008, based on Assessment-Report (RMS SE (13 December 2013))	Warning; Acute Tox 4, H332 Harmful if inhaled Acute Tox 4, H312 Harmful in contact with skin Acute Tox 4, Eye irrit. 2, H319 Causes serious eye irritation STOT SE 3; H335 May cause respiratory irritation Skin Irrit. 2, , H315 Causes skin irritation
Other information	

Classification
none

3.6.2 Assessment of effects of the product on Human Health

3.6.2.1 *Skin corrosion and irritation*

Table 19

Data waiving was acceptable for the following information requirements	
Information requirement	meta SPC 1, 2, 3 + 4: The biocidal products do not contain components classified for skin irritation or corrosivity in relevant concentrations. meta SPC 5: The biocidal products contain the following components classified for skin irritation and corrosion: Polyethylene glycol carboxymethyl dodecyl ether (6.6 %): Skin Irrit. 2 [1)] Iodine (2.0 %): Skin Irrit. 2 [1) 2)] Phosphoric acid (max. 9.12 %): Skin Corr. 1B (Skin Irrit. 2: 10 % ≤ C < 25 %) [3)] Alcohols, C12-15-branched and linear, ethoxylated propoxylated (max. 2 %): Skin Irrit 2 [1)] Based on the calculation method as described in Regulation (EC) No 1272/2008 the biocidal products have to be classified as Skin Irrit. 2, H315.
Justification	All meta SPC: A skin irritation study performed with biocidal products of this family is not required. Data waiving is acceptable since sufficient information on skin-irritating properties of the components in the biocidal product is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

[1)] According to the SDS submitted by the applicant.
[2)] According to the CAR/AR for iodine.
[3)] According to Regulation (EC) No 1272/2008.

Table 20

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	meta SPC 1, 2, 3 + 4: Non-irritant meta SPC 5: Skin-irritant
Justification for the value/conclusion	meta SPC 1, 2, 3 + 4: The biocidal products do not contain skin-irritating substances in concentrations relevant for classification. meta SPC 5: The biocidal products contain skin-irritating substances (polyethylene glycol carboxymethyl dodecyl ether, iodine, phosphoric acid, Alcohols,

	C12-15-branched and linear, ethoxylated propoxylated) in concentrations relevant for classification.
Classification of the product according to CLP	meta SPC 1, 2, 3 + 4: Not required. meta SPC 5: Skin Irrit. 2, H315

3.6.2.2 *Eye irritation*

Table 21

Data waiving was acceptable for the following information requirements	
Information requirement	meta SPC 1 + 3: The biocidal products do not contain components classified for eye irritation, eye damage or corrosivity in relevant concentrations. meta SPC 2: The biocidal products contain the following components classified for eye irritation, damage and corrosion: Isotridecanol, ethoxylated (max 0.9945 %): Eye Dam. 1 [1)] Decan-1-ol, ethoxylated (max. 0.9 %): Eye Dam. 1 [1)] Iodine (max 0.312 %[8]) from Lakeland IS20: Eye Irrit. 2 [1) 2)] Based on the calculation method as described in Regulation (EC) No 1272/2008 and the principle of additivity the biocidal products have to be classified as Eye Irrit. 2, H319. meta SPC 4: The biocidal products contain the following components classified as Eye Dam. 1, H318: max. 0.9945 % isotridecanol, ethoxylated max. 0.9 % decan-1-ol, ethoxylated Based on these components and their structural similarity and in accordance to Regulation (EC) No 1272/2008 and the principles of additivity the biocidal products have to be classified as Eye Irrit. 2, H319. The biocidal products contain further components in minor concentrations classified for eye irritation. meta SPC 5: The biocidal products contain the following components classified for eye irritation, damage and corrosion: Polyethylene glycol carboxymethyl dodecyl ether (6.6 %): Eye Dam. 1 [1)] Iodine (2.0 %): Eye Irrit. 2 [1) 2)] 2-(2-Butoxyethoxy)ethanol (max. 6.0 %): Eye Irrit. 2 [3)] Orthophosphoric acid (max. 9.1 %): Skin Corr. 1B (Eye Irrit. 2: 10 % ≤ C < 25 %) [2)] Based on the calculation method as described in Regulation (EC) No 1272/2008 the biocidal products have to be classified as Eye Dam. 1, H318.
Justification	All meta SPC: An eye irritation study performed with biocidal products of this family is not required.

8 For further information see confidential annex.

	Data waiving is acceptable since sufficient information on eye-irritating properties of the components in the biocidal products is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

[1)] According to the SDS submitted by the applicant.
[2)] According to Regulation (EC) No 1272/2008.

Table 22

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	meta SPC 1 + 3: Non-irritant meta SPC 2 + 4: Eye-irritant meta SPC 5: Eye damage
Justification for the value/conclusion	meta SPC 1 + 3: The biocidal products do not contain eye-irritating substances in concentrations relevant for classification. meta SPC 2, 4 + 5: The biocidal products contain eye-damaging/-irritating substances (meta SPC 2: ethoxylated isotridecanol, decan-1-ol, ethoxylated; iodine meta SPC 4: ethoxylated isotridecanol, ethoxylated decan-1-ol; iodine meta SPC 5: polyethylene glycol carboxymethyl dodecyl ether, iodine, 2-(2-butoxyethoxy)ethanol, orthophosphoric acid) in concentrations relevant for classification.
Classification of the product according to CLP	meta SPC 1 + 3: Not required. meta SPC 2 + 4: Eye Irrit. 2, H319 meta SPC 5: Eye Dam. 1, H318

3.6.2.3 *Respiratory tract irritation*

Table 23

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: The biocidal products do not contain components classified for respiratory irritation or corrosivity in relevant concentrations.
Justification	All meta SPC: A respiratory tract irritation study performed with biocidal products of this family is not required. Data waiving is acceptable. A study on respiratory tract irritation

	is no standard requirement for biocidal product authorisation

Table 24

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	All meta SPC: None
Justification for the value/conclusion	All meta SPC: The biocidal products contain iodine classified for respiratory irritation. However, the concentration is below the concentration limits according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	All meta SPC: Not required.

3.6.2.4 *Skin sensitization*

Table 25

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: The biocidal products do not contain components classified for skin sensitisation.
Justification	All meta SPC: A skin sensitisation study performed with biocidal products of this family is not required. Data waiving is acceptable since sufficient information on skin-sensitising properties of the components in the biocidal products of this family is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

Table 26

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	All meta SPC: Not skin-sensitising
Justification for the value/conclusion	All meta SPC: The biocidal products do not contain skin-sensitising substances.
Classification of the product according to CLP	All meta SPC: Not required.

3.6.2.5 *Respiratory sensitization (ADS)*

Table 27

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: Data on respiratory sensitisation are not available. For single components respiratory sensitisation is not reported.
Justification	All meta SPC: Suitable and harmonised in-vivo or in-vitro tests for this endpoint do not exist.

Table 28

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	All meta SPC: Respiratory sensitisation is not assumed.
Justification for the value/conclusion	All meta SPC: The biocidal products do not contain components classified for respiratory sensitisation.
Classification of the product according to CLP	All meta SPC: Not required.

3.6.2.6 *Acute toxicity*

3.6.2.6.1 Acute toxicity by oral route

Table 29

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: Information on the active substance (meta SPC 1, 2, 3 + 4: max. 0.312 %; meta SPC 5: 2.0 %): LD_{50} (oral): 315 mg/kg bw [1)] Information on co-formulants: meta SPC 1 + 3: Alkyl polyglycol ether (0.28 %): LD_{50} (oral): 300 - 2000 mg/kg bw (ATE: 500 mg/kg bw) [1)] All meta SPC: For other co-formulants the LD_{50} (oral) is expected to be above 2000 mg/kg bw. All meta SPC: Calculated LD_{50} (oral) of the biocidal product: > 2000 mg/kg bw [2)]
Justification	All meta SPC: Study not required. Sufficient information on acute oral toxicity of the single components is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

[1)] According to the SDS submitted by the applicant.
[2)] Estimated according to Regulation (EC) No 1272/2008.

Table 30

Value used in the Ris Assessment – Acute oral toxicity	
Value	All meta SPC: LD_{50} (oral) of the biocidal products: > 2000 mg/kg bw
Justification for the selected value	All meta SPC: Estimate calculated according to Regulation (EC) No 1272/2008.
Classification of the product according	All meta SPC: Not required.

to CLP	

3.6.2.6.2 Acute toxicity by inhalation

Table 31

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: Information on the active substance (meta SPC 1, 2, 3 + 4: max. 0.312 %; meta SPC 5: 2.0 %): LC_{50} (inhalation): 4.59 mg/L [1)] meta SPC 1 + 3: Information on co-formulants: Alkyl polyglycol ether (0.28 %): Based on the oral toxicity (LD_{50} (oral, ATE): 500 mg/kg bw) [1)] and in accordance to the bridging principles of the Guidance on the Application of the CLP Criteria (2015) an LC_{50} (inhalation) of 4.6 mg/L is assumed. All meta SPC: For other co-formulants the LC_{50} (inhalation) is expected to be above 5 mg/L. All meta SPC: Calculated LC_{50} (inhalation) of the biocidal products: > 5 mg/L [2)]
Justification	All meta SPC: Study not required. Sufficient information on acute inhalation toxicity of the single components is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary

[1)] According to the SDS submitted by the applicant.
[2)] Estimated according to Regulation (EC) No 1272/2008.

Table 32

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	All meta SPC: LC_{50} (inhalation) of the biocidal products: > 5 mg/L
Justification for the selected value	All meta SPC: Estimate calculated according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	All meta SPC: Not required.

3.6.2.6.3 Acute toxicity by dermal route

Table 33

Data waiving was acceptable for the following information requirements	
Information requirement	All meta SPC: Information on the active substance (meta SPC 1, 2, 3 + 4: max. 0.312 %; meta SPC 5: 2.0 %): LD_{50} (dermal): 1425 mg/kg bw [1)] meta SPC 1 + 3: Information on co-formulants: Alkyl polyglycol ether (0.28 %): Based on the oral toxicity (LD_{50} (oral, ATE): 500 mg/kg bw) [1)] and in accordance to the bridging principles of the Guidance on the Application of the CLP Criteria (2015) an LD_{50} (dermal) of 500 mg/kg bw is assumed. All meta SPC: For other co-formulants the LD_{50} (dermal) is expected to be above 2000 mg/kg bw. All meta SPC: Calculated LD_{50} (dermal) of the biocidal product: > 2000 mg/kg bw [2)]
Justification	All meta SPC: Study not required. Sufficient information on acute oral toxicity of the single components is available. According to Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing is considered not necessary.

[1)] According to the SDS submitted by the applicant.
[2)] Estimated according to Regulation (EC) No 1272/2008.

Table 34

Value used in the Risk Assessment – Acute dermal toxicity	
Value	All meta SPC: LD_{50} (dermal) of the biocidal products: > 2000 mg/kg bw
Justification for the selected value	All meta SPC: Estimate calculated according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	All meta SPC: Not required.

3.6.2.7 *Information on dermal absorption*

Table 35

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Iodine
Value(s)	12 %
Justification for the selected value(s)	The applicant proposed to use the dermal absorption studies submitted for active substance evaluation. During the BPC-WGIV2017 meeting discussion on dermal absorption of two biocidal product families with iodine as active substance was initiated. The composition of the discussed biocidal product families is comparable with the composition of the "ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILY". The majority of member states agreed to use the value of 12 % from the studies assessed during active substance approval for the following reasons. "*The results of the two dermal absorption studies demonstrated that regardless of iodophor type (i.e. alcohol ethoxylate-complexed iodine or PVP-iodine) and type and concentration of co-formulants, the dermal absorption of total iodine was ca. 12% according the most recent EFSA guidance on dermal absorption (EFSA, 2012).* *From these results it was further concluded that the dermal absorption of total iodine from biocidal products containing iodine in the form of iodophors is virtually independent of the total iodine concentration.* *Summarizing, both tested products have shown to yield the same dermal absorption value of 12% irrespective of:* *1. the iodophor type (i.e. alcohol ethoxylate-complexed iodine or PVP-iodine),* *2. the concentration of total iodine in the mixture, and* *3. the type and concentration of co-formulants, at least as long as the products are water-based.* *For this reason, in the active substance dossier on iodine, a dermal absorption of 12% was used for the calculation of human health exposure in all intended use scenarios relevant for PT3. These scenarios comprise dipping, spraying and foaming applications and include mixing and loading as well as application and post-application tasks. The use concentrations covered by these scenarios are in the range of 0.0055% to 2% available iodine."* Based on its composition, this justification is also valid for "Anti-Germ Iodine based Desinfectants Product Family". Hence, the dermal absorption value of 12 % is also valid for all members of the biocidal product family and its dilutions.

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

3.6.2.8.1 Isotridecanol, ethoxylated (CAS No 69011-36-5) in meta SPC 2 and 4

For isotridecanol, ethoxylated information is available from the ECHA Classification and Labelling Inventory and REACH dossier joint submission Reg. no. 01-2119976362-32, published: 25/06/2013, updated: 20/04/2016. This information is summarised in the table below and the confidential annex (access level: restricted to authorities; separate document). There is currently no harmonised classification & labelling available for the substance.

Table 36 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75/25 %	Default value, depending on concentration of the substance in the product (EFSA Journal 2012;10(4):2665)
Classification		
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008		No harmonised classification
Self-classifications with regard to toxicological data according to the ECHA C&L inventory REACH registration dossiers notificaton		Eye Dam. 1, H318: Causes serious eye damage. Skin Irrit. 2, H315: Causes skin irriation.
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications		Eye Dam. 1, H318 (99 % of notifiers) Acute Tox. 4, H302 (75 % of notifiers) Skin Irrit 2, H315 (10 % of notifiers)
Classification in SDS (Lakeland IS20) provided by the applicant		Eye Dam. 1, H318: Causes serious eye damage.

3.6.2.8.2 Decan-1-ol, etholxylated (CAS No 26183-52-8) in meta SPC 2 and 4

For Decan-1-ol, etholxylated (CAS No 26183-52-8), information is available from the ECHA Classification and Labelling Inventory. This information is summarised in the table below. There is currently no harmonised classification & labelling and no REACH Registration Dossier available for the substance.

Table 37 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75/25 %	Default value, depending on concentration of the substance in the product (EFSA Journal 2012;10(4):2665)

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	No harmonised classification
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications	Eye Dam. 1, H318 (99 % of notifiers)
Classification in SDS (Ifralan D8) provided by the applicant	Eye Dam. 1, H318: Causes serious eye damage.

3.6.2.8.3 Polyethylene glycol carboxymethyl dodecyl ether (CAS No 27306-90-7) in meta SPC 5

For Polyethylene glycol carboxymethyl dodecyl ether (27306-90-7), information is available from the ECHA Classification and Labelling Inventory. This information is summarised in the table below. There is currently no harmonised classification & labelling and no REACH Registration Dossier available for the substance.

Table 38 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75/25 %	Default value, depending on concentration of the substance in the product (EFSA Journal 2012;10(4):2665)

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	No harmonised classification
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications	Eye Dam. 1, H318 (97 % of notifiers) Skin Irrit 2, H315 (97 % of notifiers)
Classification in SDS (Akypo Gene Jod F) provided by the applicant	Eye Dam. 1, H318: Causes serious eye damage. Skin Irrit 2, H315: Causes skin irriation

3.6.2.8.4 Orthophosphoric Acid (CAS No 7664-38-2) in meta SPC 5

For Orthophosphoric Acid (CAS No 7664-38-2), information is available from the ECHA Classification and Labelling Inventory. This information is summarised in the table below. There is a harmonised classification & labelling available for the substance.

Table 39 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
German OEL (AGW) (inhalation)	2 mg/m^3 E	TRGS 900 (11/2016)
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75/25 %	Default value, depending on concentration of the substance in the product (EFSA Journal 2012;10(4):2665)

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	Skin Corr. 1B, H314; C ≥ 25 % Eye Irrit. 2, H319, 10 % ≤ C < 25 % Skin Irrit. 2, H315, 10 % ≤ C < 25 %
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications	Acute Tox. 4, H302 Skin Corr. 1B, H314; C ≥ 25 % Eye Irrit. 2, H319, 10 % ≤ C < 25 % Skin Irrit. 2, H315, 10 % ≤ C < 25 %
Classification in SDS (Phosphoric acid 75 % H3PO4) provided by the applicant	Skin Corr. 1B, H314: Causes severe skin burns and eye damage.

3.6.2.8.5 Alcohols, C12-15-branched and linear, ethoxylated, propoxylated (CAS No 120313-48-6) in meta SPC 5

For Alcohols, C12-15-branched and linear, ethoxylated, propoxylated (CAS No 120313-48-6), information is available from the ECHA Classification and Labelling Inventory. This information is summarised in the table below. There is currently no harmonised classification & labelling and no REACH Registration Dossier available for the substance.

Table 40 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75/25 %	Default value, depending on concentration of the substance in the product (EFSA Journal 2012;10(4):2665)

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	No harmonised classification
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications	Eye Dam. 1, H318 (56 % of notifiers) Skin Irrit 2, H315 (56 % of notifiers)

3.6.2.8.6 2-(2-butoxyethoxy)ethanol (CAS No 112-34-5) in meta SPC 5

For 2-(2-butoxyethoxy)ethanol (CAS No 112-34-5), information is available from the ECHA Classification and Labelling Inventory and REACH Registration dossier joint submission Reg. no. 01-2119475104-44, published: *03.03.2011, updated:03.06.2017*. This information is summarised in the table below. There is a harmonised classification & labelling available for the substance.

Table 41 Threshold Limits and other Values for Human Health Risk Assessment

	Value	**Source**
AEL	none	-
German OEL (AGW) (inhalation)	67 mg/m^3 E	TRGS 900 (11/2016)
Inhalative absorption	100 %	Default value
Oral absorption	100 %	Default value
Dermal absorption	75 / 25 %	Default value, depending on concentration of the substance in the product (*EFSA Journal 2012;10(4):2665)*
DNEL worker, systemic, long-term	67.5 mg/m^3	REACH Registration Dossier, 03.03.2011, last modified:03.06.2017, Endpoint respiratory irritation
DNEL, worker, dermal, long-term	83 mg/kg bw/d	REACH Registration Dossier, 03.03.2011, last modified:03.06.2017, repeated dose toxicity, chemical specific assessment factor of 24, which is lower as default value was used, justification was not verified
DNEL population, systemic , long-term	40.5 mg / m^3	REACH Registration Dossier, 03.03.2011, last modified:03.06.2017, Endpoint respiratory irritation
DNEL population, dermal, long-term	50 mg/kg bw/d	REACH Registration Dossier, 03.03.2011, last modified:03.06.2017, repeated dose toxicity, chemical specific assessment factor of 40, (lower as default value), justification was not verified

Classification	
Current, with regard to toxicological data according to Annex VI Table 3.1 of Reg. 1272/2008	Eye Irrit. 2, H319
Self-classifications with regard to toxicological data according to the ECHA C&L inventory CLP notifications	Eye Irrit. 2, H319

3.6.2.9 *Available toxicological data relating to a mixture*

Not relevant.

3.6.2.10 *Summary of effects assessment*

Table 42

Endpoint	Brief description
Skin corrosion and irritation	meta SPC 1, 2, 3 + 4: Based on information provided for the single components the biocidal products of these meta SPCs are not skin irritating. meta SPC 5: Based on information provided for the single components the biocidal products of this meta SPC have to be classified as Skin Irrit. 2, H315. This corresponds to a low hazard category for the local effect assessment.
Eye irritation	meta SPC 1 + 3: Based on information provided for the single components the biocidal products of these meta SPCs are not eye irritating. meta SPC 2 + 4 + 5: Based on information provided for the single components the biocidal products of these meta SPC have to be classified as Eye Irrit. 2, H319. This corresponds to a low hazard category for the local effect assessment. meta SPC 5: Based on information provided for the single components the biocidal products of this meta SPC have to be classified as Eye Dam. 1, H318. This corresponds to a high hazard category for the local effect assessment.
Respiratory tract irritation	All meta SPC: No data available for the biocidal products. Based on information for the single components the biocidal products are not irritating to the respiratory tract.
Skin sensitisation	All meta SPC: Based on information for the single components the biocidal products are not skin-sensitising.
Respiratory sensitisation (ADS)	All meta SPC: No data available. For the single components respiratory sensitisation was not reported.
Acute toxicity by oral route	All meta SPC: Based on information provided for the single components the LD_{50} (oral) of the biocidal products are > 2000 mg/kg bw. Classification is not required.
Acute toxicity by inhalation	All meta SPC: Based on information provided for the single components the LC_{50} (inhalation) of the biocidal products are > 5 mg/L. Classification is not requi-

	red.
Acute toxicity by dermal route	All meta SPC: Based on information provided for the single components the LD_{50} (dermal) of the biocidal products is > 2000 mg/kg bw. Classification is not required.
Information on dermal absorption	Based on the discussion during the BPC-WGIV2017 meeting on dermal absorption of comparable biocidal product families with iodine as active substance the dermal absorption value of 12 % from active substance approval is used
Available toxicological data relating to non-active substance(s)	Refer also to Sections 3.6.2.8
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not relevant.

3.6.3 Exposure assessment

3.6.3.1 *Identification of main paths of human exposure towards active substance(s) and SoC from its use in biocidal product*

Table 43

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	Not applicable	Yes	No	Not applicable	Not expected	No	Not applicable
Dermal	Not applicable	Yes	No	Not applicable	Not expected	Yes [1)]	Not applicable
Oral	Not applicable	Not applicable	No	Not applicable	Not applicable	Yes [1)]	Yes

[1)] Refers only to the use “Disinfection of animal houses by manual spraying” in meta SPC 5.

List of scenarios

Table 44

Summary table: List of Scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Teat disinfection - Dipping or Foaming	**Applies to meta SPC 1, meta SPC 2, meta SPC 3 and meta SPC 4** Primary exposure of the worker resulting from loading and application of the b.p. by using a handheld dipping cup or foaming cup and from cleaning of equipment. Secondary exposure is not expected because the task is performed by one worker and the treated area is limited to the udder of the animal.	Professional
2.	Teat disinfection - Manual spraying by trigger sprayer	**Applies to meta SPC 1 and meta SPC 2** Primary exposure of the worker resulting from loading and application of the b.p. by using a trigger spray bottle and from cleaning of the equipment. Secondary exposure is not expected because the task is performed by one worker and the treated area is limited to the udder of the animal.	Professional
3.	Teat disinfection - Manual spraying by electronic sprayer	**Applies to meta SPC 1 and meta SPC 2** Primary exposure of the worker resulting from loading and application of the b.p. by using an electronic sprayer and from cleaning of the equipment. Secondary exposure is not expected because the task is performed by one worker and the treated area is limited to the udder of the animal.	Professional
4.	Teat disinfection - Spraying by robot	**Applies to meta SPC 1 and meta SPC 2** Primary exposure of the worker resulting from loading b.p. into the reservoir of the spray roboter and cleaning of the equipment. Secondary exposure is not expected because the task is performed by one worker and the treated area is limited to the udder of the animal.	Professional
5.	Disinfection of animal houses - Manual spraying	**Applies to meta SPC 5** Primary exposure of the worker resulting from loading and application of the b.p. by using powered spray equipment and from cleaning of equipment. Secondary exposure is not expected since during the disinfection procedure only the workers performing the disinfection are present. Other personnel is expected to enter the animal house only after the treated surfaces have been dried off.	Professional
6.	Disinfection of animal houses - Manual spraying	**Applies to meta SPC 5** Secondary exposure after spray disinfection of animal houses by dermal contact and oral ingestion after skin to-mouth-contact	General public

3.6.3.1.1 Industrial exposure

For the BPF no industrial applications are intended.

3.6.3.1.2 Professional exposure

Overview of the intended applications within the five meta SPCs of the BPF

"ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILIY" is a biocidal product family (BPF) of water-based liquid disinfectants comprising of 5 meta SPCs.

The products of the meta SPCs 1, 2, 3 and 4 are used for teat disinfection of milkable animals (dairy cows, buffaloes, sheep and goats) for use after milking.
The products of meta SPC 1 and meta SPC 2 are used for teat disinfection by manual dipping using a dipping cup, manual foaming using a foam cup, manual spraying with a trigger sprayer or an electronic sprayer and spraying by robot.
The products of meta SPC 3 and 4 are used for teat disinfection by manual dipping using a dipping cup.

All members of meta SPC 1 and meta SPC 3 are ready-to-use teat disinfectants containing iodine (CAS-No.: 7553-56-2, pure: min. 995 g/kg; 0.27%).
All members of meta SPC 2 are ready-to-use teat disinfectants containing the a.s. iodine (CAS-No.: 7553-56-2, pure: min. 995 g/kg; 0,312%) and the Substances of concern (SoCs) isotridecanol, ethoxylated (CAS-No.: 69011-36-5; 1 %) and decan-1-ol, ethoxylated (CAS No. 26183-52-8; 0.9%).
All members of meta SPC 4 are ready-to-use teat disinfectants containing iodine (CAS-No.: 7553-56-2, pure: min. 995 g/kg; 0,312%) and the SoCs isotridecanol, ethoxylated (CAS-No.: 69011-36-5; 1 %) and decan-1-ol, ethoxylated (CAS No. 26183-52-8; 0.9%).

The products of meta SPC 5 are used for animal house disinfection by spraying.

All members of meta SPC 5 are concentrates containing the active substance iodine (CAS-No.: 7553-56-2, pure: min. 995 g/kg; 2 %) and the SoCs orthophosphoric acid (7664-38-2; 9.12 %), 2-(2-butoxyethoxy)ethanol (butyldiglycol) (CAS-No.:112-34-5; 6 %), polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7; 7%) and alcohols, C12-15 branched and linear, ethoxylated, propoxylated (CAS No: 120313-48-6; 2%).

The summary Table 45 gives an overview of the applications in meta SPCs 1 to 5 of the BPF. Please note that the number of the scenario is not identical with the use number.

Assessment of inhalation exposure to vapour of iodine
Please note that the assessment of "ANTI-GERM IODINE BASED DISINFECTANTS PRODUCT FAMILIY" was done prior to the discussion of the iodine teat disinfectant (union authorisations) on EU level. On EU level it was concluded that inhalation exposure to vapours of iodine can be considered negligible, and therefore inhalation exposure to vapours does not need to be assessed.
A statement of the IRG PT3 subgroup is available, which sums up the considerations on iodine vapours, and which was the basis of the EU agreements.

This additional information on the complex bound nature of the active substance iodine was provided by the applicant by June 2018, but is not considered for the professional exposure assessment in the PAR. In this PAR the inhalation exposure to vapour of iodine is assessed using ConsExpo.
It is important to note that the inhalation exposure to iodine vapour as calculated by ConsExpo is very low and does not lead to the introduction of risk mitigation measures. Therefore we decided not to delete the assessed inhalation exposure to vapour of iodine.

General Information on meta SPC 1 to 4

The products of meta SPC 1 to 4 are marketed in different package sizes:

- Jerry can containing 1 to 35 kg product
- drum containing 35 to 240 kg product
- IBC containing 1000 kg product

The concentration of the a.s. iodine is:

- 0.27 % for the products in meta SPC 1 and meta SPC 3
- max 0.312 %[8] for the products in meta SPC 2 and meta SPC 4.

Exposure assessment was carried out for an a.s. concentration of 0.312 % iodine which is applicable for the products in meta SPCs 2 and 4. Due to the higher a.s. concentration of the products in meta SPCs 2 and 4 it can be regarded as a worst-case assumption for the applications in meta SPC 1 and in meta SPC 3.
The exposure assessment is usually based on the harmonised document “Biocides Human Health Exposure methodology” (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

The dermal and inhalation exposure to the a.s iodine are assessed separately for the different application techniques and will thus be described in individual subsections of the current section.
In Annex 4.2 the details of the exposure calculations to the a.s. iodine for the professional user are laid out.

Due to local effects of the SoCs isotridecanol, ethoxylated and decan-1-ol, ethoxylated a qualitative local risk assessment is performed for meta SPC 2 and described in chapter 3.6.4.4.

General Information on meta SPC 5

The products of meta SPC 5 are marketed in different package sizes:

- Jerrycan containing 1 kg to 35 kg of product
- drum containing 35 kg to 240 kg of product
- IBC containing 1000 kg

The exposure to the a.s iodine and the SoCs, orthophosphoric acid and 2-(2-butoxyethoxy)ethanol (butyldiglycol) are assessed quantitatively and described in chapter 3.6.4.4.
The exposure assessment is usually based on the harmonised document “Biocides Human Health Exposure methodology” (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

In Annex 4.2 the details of the exposure calculations to the a.s. iodine for the professional user are laid out.

Due to local effects of the SoCs orthophosphoric acid, 2-(2-butoxyethoxy)ethanol (butyldiglycol), polyethylene glycol carboxymethyl dodecyl ether and alcohols, C12-15 branched and linear, ethoxylated, a qualitative local risk assessment is performed and described in chapter 3.6.4.4. In addition for the SoC orthophosphoric acid and 2-(2-butoxyethoxy)ethanol (butyldiglycol) the quantitative inhalation exposure is assessed.

Table 45

Summary table: Presentation of the exposure assessment Scenarios with the same scenario no. were assessed identically, even if they appear in more than one SPC.			
meta SPC	**Use No.**	**Scenario No.**	**Intended applications**
meta SPC 1	1.1/1.2	1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping or by manual foaming = Scenario Teat disinfection - Dipping or Foaming
	1.3	2	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer = Scenario Teat disinfection - Manual spraying by trigger sprayer
	1.4	3	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer = Scenario Teat disinfection - Manual spraying by electronic sprayer
	1.5	4	Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot = Scenario Teat disinfection - Spraying by robot
meta SPC 2	1.1/1.2	1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping or by manual foaming = Scenario Teat disinfection - Dipping and Foaming
	1.3	2	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using a trigger sprayer = Scenario Teat disinfection - Manual spraying by trigger sprayer
	1.4	3	Teat disinfection of milkable animals: Post-milking teat disinfection by manual spraying using an electronic sprayer = Scenario Teat disinfection - Manual spraying by electronic sprayer
	1.5	4	Teat disinfection of milkable animals: Post-milking teat disinfection by automated spraying by robot = Scenario Teat disinfection - Spraying by robot
meta SPC 3	1.1	1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping = Scenario Teat disinfection - Dipping or Foaming
meta SPC 4	1.1	1	Teat disinfection of milkable animals: Post-milking teat disinfection by manual dipping = Scenario Teat disinfection - Dipping or Foaming
meta SPC 5	2.1	5	Disinfection of animal houses by manual spraying = Scenario Disinfection of animal houses - Manual spraying

Scenario 1 – Teat disinfection - Dipping and Foaming

Description

Scenario 1, as described in this chapter, applies to the respective application of the four meta SPCs 1, to 4. The concentration of the active substance iodine is 0.27 % for the products in meta SPC 1 and meta SPC 3. Exposure assessment was carried out for an a.s. concentration of 0.312 % iodine which is applicable for the products in meta SPCs 2 and 4. Because of the higher a.s. concentration this scenario covers dipping and foaming applications of the b.p. in meta SPC 1 and meta SPC 3 as well.
The exposure assessment is carried out based on the Recommendation no. 13 of the BPC Ad hoc Working Group on Human Exposure about "Exposure assessment of teat disinfection products for vetenary hygiene (PT 3)"

The products are ready-to-use solutions which are filled into the reservoir of a specifically designed dipping cup and are then used for disinfection of teats by manual dipping after milking.

The products may also be used for teat disinfection by manual foaming. For this application the product is also filled into a reservoir of a foaming cup which is then used for disinfection of teats by manual foaming. The foam is generated by squeezing the product out of the reservoir into the upper compartment of the foaming cup. The application rate for dipping of cow teats is 10 ml of b.p. per animal whereas the application rate for foaming is 5 ml per animal. Therefore the exposure during teat disinfection by manual foaming is covered by scenario 1 "Teat disinfection - Dipping and Foaming" taking into account of 10 ml of b.p.

Dermal exposure

Exposure to skin is expected to mainly occur during the loading phase.
HEADhoc recommendation 13 advises the "Mixing and loading model 4" (TNsG on Human Exposure, Human Exposure Expert Group (HEEG) opinion) to assess the manual loading of a dipping/foaming cup. A mixing step is not necessary as the products of the BPF are ready-to-use solutions. Re-filling of the equipment with the RTU will be covered within this mixing and loading step.
Exposure to skin is considered to occur mainly during the loading phase of the dipping cup. Dipping cups are normally designed specifically for this task. This cup has an upper compartment for application of the dip and a lower compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or a treated teat is avoided.

In addition, exposure of hands during cleaning of the equipment has to be considered. After application, a small amount of diluted product will remain in the application equipment. Therefore according to HEADhoc recommendation 13 dermal exposure during the post-application is assessed by the RISKOFDERM toolkit for Connecting lines ("HEEG Opinion 1 - HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale").
Exposure by inhalation
Exposure to aerosol is not expected during loading of the dipping cup, the dipping application and the cleaning step during the post-application phase. Thus it is not assessed.

Exposure to vapour occurs during the loading phase due to the vapour pressure of the active substance iodine of 40.7 Pa at 25 °C. A calculation of the nearfield (1 m^3) exposure of the worker to the a.s. iodine is calculated using the consumer exposure model ConsExpo web model "Inhalation- exposure to

vapour- evaporation constant surface area model" which is applicable to assess the volatile part of the active substance.
Exposure to vapour during the dipping or foaming application is also assessed based on HEADhoc recommendation 13 by the consumer exposure model ConsExpo web model "Inhalation- exposure to vapour- evaporation constant surface area model". Evaporation from the teats of 82 milk producing cows is considered (an average cow herd size of 100 animals, a lactation period of dairy cows of 270 to 300 days resulting in 82 milk producing cows per day).
During the post-application phase when the equipment is cleaned inhalation exposure to vapour is assessed to be negligible in relation to the loading and application phase.

Exposure to the eyes

Exposure to the eyes may occur during the loading phase. Eye contact in consequence of splashes during filling of the product into the reservoir of the dipping or foaming cup cannot be excluded. Eye exposure is only of relevance for the products in meta SPCs 2 and 4 because they are classified with H319.

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 50.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2 of this PAR.
For risk characterisation, see chapter 3.6.4.4.

Further information and considerations

The classification of the b.p in meta SPCs 2 and 4 requires additional assessment of local risks (chapter 3.6.4.4). Local risk assessment has indicated a risk for serious eye irritiation, thus eye protection is required.
Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.
The use of a dosing pump for filling the product into the application equipment is recommended. This is a technical measure to reduce dermal exposure in comparison to manual decanting of the product.

Table 46

Details of Scenario 1	
Parameters	**Value**
Concentration of a.s. iodine in b.p.	0.312 %
Density of the b.p.	1.05 g/cm³ (25°C)
Number of tasks	1
Total amount of b.p. per day	1722 g (20 ml per cow)
Indicative value corresponding to 5 L of b.p.	0.2 ml
ConsExpo web parameters for the loading phase	
Room volume	1 m^3
Exposure duration	0.75 min
Application duration	0.25 min
Product amount	5 kg
Ventilation rate	4 / h
Release area	20 cm^2
Mass transfer rate	Thibodeaux
ConsExpo web parameters for the application phase	
Room volume	168 m^3
Ventilation rate	4 / h
Application duration	180 min
Exposure duration	180 min
Release area[1)]	14432 cm^2
Mass transfer rate	Thibodeaux

[1)] Release area: Total area of 4 teats of all 82 cows (4 x 44 cm^2 x 82)

Scenario 2 – Teat disinfection - Manual spraying by trigger sprayer

Description

Scenario 2, as described in this chapter, applies to the respective application of meta SPC 1 and meta SPC 2. The concentration of the a.s. iodine is 0.27 % for the products in meta SPC 1. Exposure assessment was carried out for an a.s. concentration of 0.312 % iodine which is applicable for the products in meta SPCs 2. Because of the higher a.s. concentration this scenario covers the manual spraying application by hand-held trigger spray bottle of the b.p. in meta SPC 1 as well.

The products are ready-to-use solutions which can directly be used for disinfection of teats by manual spraying of the cow teats after milking.

The exposure assessment is carried out based on the Recommendation no. 13 of the BPC Ad hoc Working Group on Human Exposure about “Exposure assessment of teat disinfection products for vetenary hygiene (PT 3)”

The reservoir of a hand-held trigger spray bottle is filled with the RTU from a bigger vessel e.g. a jerrycan. Then the spray head is screwed on the bottle and the bottle is used for manual disinfection of teats. The spray nozzle of the bottle is directed upwards so that the spray is applied in upward direction on the teats. The application rate is 15 ml of b.p. per animal for usage of the hand-held trigger spray bottle. After the application the equipment i.e. the hand-held trigger spray bottle is manually cleaned.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During the loading procedure dermal exposure may occur due to loading of the hand-held trigger spray bottle.
HEADhoc recommendation 13 advises the “Mixing and loading model 4” (TNsG on Human Exposure, Human Exposure Expert Group (HEEG) opinion) to assess the loading of a hand-held trigger spray bottle. A mixing step is not necessary as the products of the BPF are ready-to-use solutions.

Since the spray cone is directed in upwards direction and the handle is in close proximity to the spray nozzle it can be expected that dermal exposure with spray droplets occurs during the application phase. Dermal exposure during teat disinfection of milkable animals by manual spraying is assessed by using the “Consumer spraying and dusting model 2” (TNsG on Human Exposure) as recommended in HEADhoc 13. The model is based on measurement data collected indoors during spraying of horizontal and vertical surfaces with a hand-held trigger sprayer by non-professionals and provides data of potential hand and forearm as well as legs, feet and face exposure. According to HEADhoc 13 the spraying time per cow/event is 10 seconds. An average cow herd size of 100 animals, a lactation period of dairy cows of 270 to 300 day and thus 82 milk producing cows per day are assumed. This translates to 28 minutes exposure duration for post-milking teat disinfection twice per day.
In addition, exposure of hands during cleaning of the equipment has to be considered. After application, a small amount of diluted product will remain in the application equipment. Therefore dermal exposure during the post-application is assessed by the RISKOFDERM toolkit for Connecting lines (“HEEG Opinion 1 - HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale”) as recommended in HEADhoc 13.

Inhalation exposure

During the application phase teat disinfection is carried out by spraying in upwards direction with a hand-held trigger spray bottle against the teat of the animal. Since the face of the worker is directed towards the udder of the animal it can be expected that inhalation exposure to the spray aerosol occurs. Inhalation exposure to aerosol during teat disinfection by manual spraying is calculated for a.s. using the values of the “Consumer spraying and dusting model 2”.

Exposure to vapour occurs during the loading phase due to the vapour pressure of the active substance iodine of 40.7 Pa at 25 °C. According to HEADhoc 13 a calculation of the nearfield (1 m^3) exposure of the worker to the a.s. iodine is performed for iodine using the consumer exposure model model ConsExpo web „Exposure to vapour - evaporation constant surface area model “” which is applicable to assess the volatile part of the active substance. Inhalation exposure to vapour during the loading phase is assessed based on HEADhoc 13 analogously to Scenario 1 - Teat disinfection - Dipping and Foaming.

Exposure to vapour during the spray application is also assessed by the consumer exposure model ConsExpo web model “Inhalation- exposure to vapour- evaporation constant surface area model” as well. Evaporation from the teats of 82 milk producing cows is considered (an average cow herd size of 100 animals, a lactation period of dairy cows of 270 to 300 days resulting in 82 milk producing cows per day).

During the post-application phase when the equipment is cleaned inhalation exposure to aerosol and vapour is assessed to be negligible in relation to the loading and application phase.

Exposure to the eyes

Exposure to the eyes may occur during the loading phase. Eye contact in consequence of splashes during filling of the product into the hand-held trigger spray bottle or the reservoir of the electronic sprayer cannot be excluded. Eye exposure is only of relevance for the products in meta-SPC 2 because they are classified with H319.

Table 47

Details of Scenario 2	
Parameters	**Value**
Concentration of a.s. iodine in b.p RTU.	0.312 %
Density of the b.p.	1.02 g/cm³ (25°C)
Number of events	1
Amount of b.p. per day	2510 g (30 ml per cow)
Indicative value corresponding to 5 L of b.p.	0.2 ml
Duration for cleaning	5 min
ConsExpo web parameters for the loading phase	
Room volume	1 m^3
Exposure duration	0.75 min
Application duration	0.25 min
Product amount	5 kg
Ventilation rate	2 / h
Release area	20 cm^2
Mass transfer rate	Thibodeaux
ConsExpo web parameters for the application phase	
Room volume	420 m^3
Ventilation rate	4 / h
Application duration	180 min
Exposure duration	180 min
Release area[1)]	14432 cm^2
Mass transfer rate	Thibodeaux

[1)] Release area: Total area of 4 teats of all 82 cows (4 x 44 cm^2 x 82)

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 50.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2 of this PAR.
For risk characterisation, see chapter 3.6.4.4.

Further information and considerations

The classification of the b.p in meta SPC 2 requires additional assessment of local risks (see chapter 3.6.4.4). Local risk assessment has indicated a risk for eye damages, thus eye protection is required.
The quantitative exposure assessment has indicated significant exposure of hands and body for the tasks of manual spraying by trigger spray bottle. As a consequence, a refined exposure assessment was performed, taking the following safety measures into account for Tier 2 to address systemic risks:

protective gloves (EN 374) The use of a dosing pump for filling the product into the application equipment is recommended. This is a technical measure to reduce dermal exposure in comparison to manual decanting of the product.

Scenario 3 – Teat disinfection - Manual spraying by electronic sprayer

Description

Scenario 3, as described in this chapter applies to the respective application of meta SPC 1 and meta SPC 2. The concentration of the a.s. iodine is 0.27 % for the products in meta SPC 1. Exposure assessment was carried out for an a.s. concentration of 0.312 % iodine which is applicable for the products in meta SPCs 2. Because of the higher a.s. concentration this scenario covers the spraying application by electronic sprayer of the b.p. in meta SPC 1 as well.

The exposure assessment is carried out based on the Recommendation no. 13 of the BPC Ad hoc Working Group on Human Exposure about “Exposure assessment of teat disinfection products for vetenary hygiene (PT 3)”

The products are ready-to-use solutions which can directly be used for disinfection of teats by electronic spraying of the cow teats after milking. The application rate is 15 ml of b.p. per animal for usage of the electronic sprayer. For loading of the system the sucking lance of the electronic sprayer is inserted into the jerrycan containing the RTU teat disinfectant. The system includes a hand-held spray handle and the b.p. is sprayed in upwards direction on the teats of the animal.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling. Dermal exposure is calculated as described in HEADhoc recommendation 13.

During the loading procedure dermal exposure may occur insertion of the sucking lance into the vessel containing the RTU which may be a jerrycan, a drum or an IBC.
Opinion. For the assessment of the loading the exposure model RISKOFDERM Toolkit Connencting Lines) is used. A mixing step is not necessary as the products of the BPF are ready-to-use solutions.

Since the spray cone is directed in upwards direction and the handle is in close proximity to the spray nozzle it can be expected that dermal exposure with spray droplets occurs during the application phase. Dermal exposure during teat disinfection of milkable animals by manual spraying is assessed by using the “Consumer spraying and dusting model 2” (TNsG on Human Exposure). The model is based on measurement data collected indoors during spraying of horizontal and vertical surfaces with a hand-held trigger sprayer by non-professionals and provides data of potential hand and forearm as well as legs, feet and face exposure. Although the electronic sprayer has a working pressure of 2 to 5 bar the application is covered by the assessment with the consumer spraying model because it is assumed that the pressure at the spray nozzle where dermal exposure is expected to occur is lower than the working pressure of the system. According to HEADhoc recommendation 13 the spraying time per cow/event is 10 seconds. An average cow herd size of 100 animals, a lactation period of dairy cows of 270 to 300 day and thus 82 milk producing cows per day are assumed. This translates to 28 minutes exposure duration for post-milking teat disinfection twice per day.
In addition, exposure of hands during cleaning of the equipment has to be considered. After application, a small amount of diluted product will remain in the application equipment. Therefore dermal exposure during the post-application is assessed by the RISKOFDERM toolkit for Connecting lines (“HEEG Opinion 1 - HEEG Opinion on the use of available data and models for the assessment of the exposure

of operators during the loading of products into vessels or systems in industrial scale") based on HEADhoc 13.

Inhalation exposure

During the application phase teat disinfection is carried out by spraying in upwards direction with a handle against the teat of the animal. Since the face of the worker is directed towards the udder of the animal it can be expected that inhalation exposure to the spray aerosol occurs. Inhalation exposure to aerosol during teat disinfection by electronic spraying is calculated based on the HEADhoc recommendation 13 using the values of the "Consumer spraying and dusting model 2".

Exposure to vapour occurs during the loading phase due to the vapour pressure of the active substance iodine of 40.7 Pa at 25 °C. According to HEADhoc 13 a calculation of the nearfield (1 m^3) exposure of the worker to the a.s. iodine is performed for iodine using the consumer exposure model model ConsExpo web „Exposure to vapour - evaporation constant surface area model "" which is applicable to assess the volatile part of the active substance. Inhalation exposure to vapour during the loading phase is assessed analogously to Scenario 1 - Teat disinfection - Dipping and Foaming.

Exposure to vapour during the spray application is also assessed by the consumer exposure model ConsExpo web model "Inhalation- exposure to vapour- evaporation constant surface area model" as well. Evaporation from the teats of 82 milk producing cows is considered (an average cow herd size of 100 animals, a lactation period of dairy cows of 270 to 300 days resulting in 82 milk producing cows per day).

During the post-application phase when the equipment is cleaned inhalation exposure to aerosol and vapour is assessed to be negligible in relation to the loading and application phase.

Exposure to the eyes

Exposure to the eyes may occur during the loading phase. Eye contact in consequence of splashes during filling of the product into the hand-held trigger spray bottle or the reservoir of the electronic sprayer cannot be excluded. Eye exposure is only of relevance for the products in meta-SPC 2 because they are classified with H319.

Table 48

Details of Scenario 3	
Parameters	**Value**
Concentration of a.s. iodine in b.p RTU.	0.312 %
Density of the b.p.	1.02 g/cm³ (25°C)
Number of loading tasks	1 per day
Duration for cleaning	5 min
ConsExpo web parameters for the loading phase	
Room volume	1 m^3
Exposure duration	0.75 min
Application duration	0.25 min
Product amount	5 kg
Ventilation rate	4 / h
Release area	20 cm^2
Mass transfer rate	Thibodeaux
ConsExpo web parameters for the application phase	
Room volume	168 m^3
Ventilation rate	4 / h
Application duration	180 min
Exposure duration	180 min
Product amount	2509 g
Release area[1)]	14432 cm^2
Mass transfer rate	Thibodeaux

[1)] Release area: Total area of 4 teats of all 82 cows (4 x 44 cm^2 x 82)

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 50.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2 of this PAR.
For risk characterisation, see chapter 3.6.4.4.

Further information and considerations

The classification of the b.p in meta SPC 2 requires additional assessment of local risks (see chapter 3.6.4.4). Local risk assessment has indicated a risk for eye damages, thus eye protection is required.
Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

The use of a dosing pump for filling the product into the application equipment is recommended. This is a technical measure to reduce dermal exposure in comparison to manual decanting of the product.

Scenario 4 – Teat disinfection - Spraying by robot

Description

Scenario 4, as described in this chapter, applies to the respective application of meta SPC 1 and meta SPC 2. The concentration of the active substance iodine is 0.27 % for the products in meta SPC 1. Exposure assessment was carried out for an a.s. concentration of 0.312 % iodine which is applicable for the products in meta SPCs 2. Because of the higher a.s. concentration this scenario covers the spraying by robot application of the b.p. in meta SPC 1 as well.
The exposure assessment is carried out based on the Recommendation no. 13 of the BPC Ad hoc Working Group on Human Exposure about “Exposure assessment of teat disinfection products for vetenary hygiene (PT 3)”

The products of meta SPC 1 and meta SPC 2 are ready-to-use solutions which can directly be used for teat disinfection of milkable animals by automatic spraying. For this purpose the sucking lance of the spraying roboter is inserted into the vessel containing the RTU which may be a jerrycan, a drum or an IBC. Disinfection of the teats is carried out automatically by the robot. The application rate is 15 ml of b.p. per animal. During the post-application phase the system is cleaned with water.

Dermal exposure

Exposure to skin is considered to occur during the loading phase and the post-application phase. It is calculated based on the HEADhoc recommendation 13. According to the “HEEG Opinion 1 - HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale”, a recommended approach for automated transfer and pumping is the RISKOFDERM toolkit for connecting lines. A mixing step is not necessary as the products are ready-to-use solutions.

Because of the automatisation of the spraying procedure dermal exposure is not expected during the application phase.

Exposure of hands during cleaning of the equipment has to be considered. After application, a small amount of diluted product will remain in the application equipment. Therefore dermal exposure during the post-application is assessed by the RISKOFDERM toolkit for connecting lines (“HEEG Opinion 1 - HEEG Opinion on the use of available data and models for the assessment of the exposure of operators during the loading of products into vessels or systems in industrial scale”).

Exposure by inhalation

Inhalation exposure to aerosol and vapour is assessed to be negligible due to the automatisation of the process and the corresponding short potential exposure duration.

Exposure to the eyes

Due to the automatisation of the spraying by robot eye contact is excluded. This is of relevance for meta-SPC 2.

Table 49

Details of Scenario 4	
Parameters	**Value**
Concentration of a.s. iodine in b.p.	0.312 %
Density of the b.p.	1.02 g/cm³ (25°C)
Duration for loading	1 min
Duration for cleaning	5 min

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 50.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2 of this PAR.
For risk characterisation, see chapter 3.6.4.4.

Further information and considerations

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking the use of protective gloves into account.

Further information and considerations on scenarios 1 to 4

Table 50

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m^3]	**Estimated external dermal exposure [mg/day]**
Scenario 1 Teat disinfection - Dipping and Foaming	Tier 1:-	8.25x 10^{-3}	0.67
	Tier 2: • RMM: Protective gloves*)	8.25x10^{-3}	0.07
Scenario 2 Teat disinfection - Manual spraying by trigger sprayer	Tier 1:-	1.02x10^{-2}	4.73
	Tier 2: • RMM: Protective gloves	1.02x10^{-2}	1.25
Scenario 3 Teat disinfection - Manual spraying by electronic sprayer	Tier 1:-	1.02x10^{-2}	4.10
	Tier 2: • RMM: Protective gloves*)	1.02x10^{-2}	1.19
Scenario 4 Teat disinfection- Spraying by robot	Tier 1:-	not expected	1.76x10^{-2}
	Tier 2: • RMM: Protective gloves*)	not expected	1.76x10^{-3}

***)** According to the calculation performed in Tier 1, specified protective equipment is not necessary; a risk for professional users is unlikely (for details see chapter 3.6.4.4).

Scenario 5 – Disinfection of animal houses - Manual spraying

Description

The products of **meta SPC 5** of the BPF are disinfectant concentrates which have to be diluted prior to application. Subsequently, the application liquids are sprayed with medium spraying pressure (4 to 7 bar) using powered spray equipment.

Dermal exposure

Exposure to skin is considered to occur during all phases of handling.

During the application process exposure via skin seems likely, mainly due to the deposition of the generated droplets on the work clothing and the hands of the operator. The application method of manual spraying for the a.s. iodine is assessed using “Spraying model 2” (TNsG on Human Exposure) and the applicant also propounds this model to assess the described exposure situation. The model is based on measurement data collected during spraying with hand-held spraying device and medium spraying pressure (4-7 bar) and provides data of potential body and actual hand exposure (measurements of hand exposure inside gloves). The model covers spray application indoors and outdoors, in overhead and downward direction. It relates to application of remedial biocides to structural timber and masonry in industrial, recreational and residential settings. It already contains the mixing and loading phase. Therefore, a separate calculation for this phase has not been performed.

In addition, exposure of hands during cleaning of the equipment has to be considered, although it represents a minor part of the total dermal exposure. This post-application phase is assessed using the indicative values given by Marquart et al. for cleaning of spray guns.

Exposure by inhalation

Exposure to aerosol occurs during the mixing and loading phase and the application phase (spraying) and is calculated for the a.s.iodine and the substances of concern orthophosphoric acid and 2-(2-butoxyethoxy)ethanol (butyldiglycol) using the values from “Spraying model 2”. The model already contains the mixing and loading phase.
As the inhalative reference value of the SoC orthophosphoric acid for risk assessment (see chapters 3.6.2 and 3.6.2 and 3.6.4) is based on a corresponding measurement for airborne particles only the assessment of inhalation exposure to aerosol is considered to be sufficient for this SoC.

In addition, exposure to vapour occurs during the application phase for the a.s. iodine and the SoC 2-(2-butoxyethoxy)ethanol (butyldiglycol) and is calculated using the consumer exposure model ConsExpo web model “Exposure to vapour: evaporation - increasing area” which is applicable to assess the volatile part of these two substances.

Exposure to the eyes

Exposure to the eyes may occur during the mixing and loading phase and during the spray application. Eye contact in consequence of splashes during mixing and loading of the product into the reservoir of a powered spraying device cannot be excluded. Eye contact in consequence of splashes during the spray application can also not be excluded.

Table 51

Details of Scenario 5	
Parameters	Value
Concentration of a.s. iodine in b.p.	2 %
Concentration of SoC orthophosphoric acid in b.p.	9.12 %
Concentration of SoC (2-butoxyethoxy)ethanol (butyldiglycol) in b.p.	6.00 %
Concentration of b.p. in application liquid	2 %
Density of the b.p.	1.075 g/cm³ (25°C)
Exposure duration	180 min
ConsExpo web parameters for the application phase	
Room volume	9380 m^3
Ventilation rate	1.3 / h
Application duration	180 min
Product amount	1750 kg
Exposure duration	180 min
Release area	3500 m^2
Mass transfer rate	Thibodeaux

Calculations

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 52, Table 53 and Table 54.
For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.2 of this PAR.
For risk characterisation, see chapter 3.6.4.4.

Further information and considerations

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.4). The local toxicity profiles of the a.s. iodine as well as the SoCs orthophosphoric acid (CAS No: 7664-38-2), 2-(2-butoxyethoxy)ethanol (CAS No: 112-34-5) polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7) and alcohols, C12-15 branched and linear, ethoxylated, propoxylated (CAS No: 120313-48-6) are considered in the local risk assessment. These SoCs contribute to the classification of the biocidal products covered by meta SPC 5 with H315 (Causes skin irritation) and H318 (Causes serious eyedamage). Local risk assessment has indicated a risk for eye damages, thus eye protection is required.
The quantitative exposure assessment has indicated significant exposure of hands and body. As a consequence, a refined exposure assessment was performed, taking the following safety measures into account for Tier 2 to address systemic risks: protective gloves (EN 374) and a coated protective coverall (type 6, EN 13034).

Table 52

Summary table: estimated exposure from professional uses to the a.s.. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m^3]	**Estimated external dermal exposure [mg/day]**
active substance iodine	Tier 1:-	0.03	35.72
	Tier 2: RMM: Protective gloves, protective coverall	0.03	2.17

Table 53

Summary table: estimated exposure from professional uses to the SoC 1. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m^3]	**Estimated external dermal exposure [mg/day]**
SoC 1 orthophosphoric acid	Tier 1:-	0.052	n.a.
	Tier 2: RMM: Protective gloves, protective coverall	0.052	n.a.

Table 54

Summary table: estimated exposure from professional uses to the SoC 2. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.			
Exposure scenario	**Tier/PPE**	**a.s. 1**	
		Estimated external inhalation exposure [mg/m^3]	**Estimated external dermal exposure [mg/day]**
Soc 2 -(2-butoxyethoxy)ethanol (butyldiglycol)	Tier 1:-	0.039	n.a.
	Tier 2: RMM: Protective gloves, protective coverall	0.039	n.a.

- **<u>Combined scenarios</u>**

Not applicable. For exposure of professional users refer to Table 50, 52-54.

3.6.3.1.3 Non-professional exposure

For the BPF no non-professional applications are intended.

3.6.3.1.4 Exposure of the general public

- **Scenario 6**

Secondary exposure of the general public is limited to iodine from biocidal products of Meta SPC 5. Secondary exposure to the biocidal products of Meta SPC 1 to 4 is not expected for the general public. For SoCs a quantitative exposure assessment is not performed since harmonised reference values are not available and the categorisation as SoC is based on a local effect (eye irritation). Based on the dilution of the biocidal product during application no human health risk is expected for the general public by secondary exposure to the SoC.

Table 55

Description of Scenario 6		
The general public has normally no access to animal houses due to hygienic and safety reasons. This might be different in small farms, where the family and guests lives nearby the animal houses. Other persons than the farmer (visiting adults, playing children) may get in contact to treated surfaces occasionally (acute exposure). Therefore, secondary exposure of the general public after manual spraying has to be considered. Based on the fact that iodine is complex-bound inhalation exposure is considered not relevant. Oral exposure may occur if persons lick their hands after dermal contact. Exposure of smaller children toddler is not assessed. It is not expected that they will enter animal houses. The biocidal product is applied on all surfaces. The biocidal product containing 2 % available iodine is diluted 50-fold resulting in a iodine concentration of 0.04 %.The application rate of this dilution is 400 mL/m^2. It is assumed that adults or children touch treated surface with one hand palm. In case of wet surfaces a transfer factor for dislodgeable residues of 100 % is assumed (Tier 1). In case of dried surfaces a factor of 55 % for white smooth glazed tiles is used for calculations (Tier 2Based on the discussion during the BPC-WGIV2017 meeting on dermal absorption of comparable biocidal product families with iodine as active substance the dermal absorption value of 12 % from active substance approval is used. The density of the application solution is assumed to be 1 g/cm^3. Under the given conditions oral exposure is considered unlikely. As a worst case it can be assumed that a person licks some fingertips after dermal contact. It is assumed that the licked surface of the fingertips is about 5 cm^2 for both children and adults. For animal housing disinfection inhalation exposure of the general public during application is not expected since they do not have access. Based on the common air exchange rates in animal housings exposure of the general public after application is considered not relevant.		
	Parameters	Value
Tier 1	Available iodine in the concentrate	2 %
	Available iodine in the 50-fold in-use-dilution	0.04 %
	Application rate of the dilution (applicant)	400 mL/m^2
	Applied iodine per cm^2	0.016 mg/cm^2

	Surface one hand palm, adult (based on surface of both hands: 820 cm^2, HEEG opinion No 17, Default human factor values for use in exposure assessments for biocidal products 2013)	205 cm^2
	Surface one hand palm, child (based on surface of both hands: 427.8 cm2, HEEG opinion No 17, Default human factor values for use in exposure assessments for biocidal products 2013)	107 cm^2
	Transfer coefficient for dislodgeable residues wet surface (worst case)	100 %
	Body weight adult (HEEG opinion No 17, Default human factor values for use in exposure assessments for biocidal products 2013)	60 kg
	Body weight child (HEEG opinion No 17, Default human factor values for use in exposure assessments for biocidal products 2013)	23.9 kg
	Surface of licked fingertips (expert judgement)	5 cm^2
	Dermal absorption (CAR, 2013, BPC-WGIV 2017)	12 %
	Oral absorption (CAR, 2013)	100 %
Tier 2	Transfer coefficient for dislodgeable residues (smooth glazed tiles, Biocides Human Health Exposure Methodology, 2015)	55 %
	For other parameters refer to Tier 1	

Calculations for Scenario 6

Dermal exposure

Systemic dermal exposure = applied iodine x surface hand palm x transfer coefficient dislodgeable residues x dermal absorption / body weight

Tier 1

Adults

Systemic dermal exposure = 0.016 mg x 205 cm^2 x 100 % x 12 % / 60 kg

= 0. 006560 mg/kg bw

Children

Systemic dermal exposure = 0.016 mg x 107 cm^2 x 100 % x 12 % / 23.9 kg

= 0. 00860 mg/kg bw

Tier 2

Adults

Systemic dermal exposure = 0.016 mg x 205 cm^2 x 55 % x 12 % / 60 kg

= 0. 00361mg/kg bw

Children

Systemic dermal exposure = 0.016 mg x 107 cm^2 x 55 % x 12% / 23.9 kg

= 0. 00473 mg/kg bw

Oral exposure

Systemic oral exposure = applied iodine x surface fingertips x transfer coefficient dislodgeable residues x transfer coefficient hand-to-mouth x oral absorption / body weight

Tier 1

Adults

Systemic oral exposure = 0.016 mg x 5 cm^2 x 100 % x 100 % x 100 % / 60 kg

= 0.00133 mg/kg bw

Children

Systemic oral exposure = 0.016 mg x 5 cm^2 x 100 % x 100 % x 100 % / 23.9 kg

= 0.00335 mg/kg bw

Tier 2

Adults

Systemic oral exposure = 0.016 mg x 5 cm^2 x 55 % x 100 % x 100 % / 60 kg

= 0.00073 mg/kg bw

Children

Systemic oral exposure = 0.016 mg x 5 cm^2 x 55 % x 100 % x 100 % / 23.9 kg

= 0.00184 mg/kg bw

Total systemic exposure

Tier 1

Adults

Total systemic exposure = 0.00789 mg/kg bw

Children

Total systemic exposure = 0.01195 mg/kg bw

Tier 2

Adults

Total systemic exposure = 0.00434 mg/kg bw

Children

Total systemic exposure = 0.00657 mg/kg bw

Table 56

Summary table: systemic exposure for the general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 6 Adult	1	-	0.00656 mg/kg bw	0.00133 mg/kg bw	0.00789 mg/kg bw
Scenario 6 Child	1	-	0.00860 mg/kg bw	0.00335 mg/kg bw	0.01195 mg/kg bw
Scenario 6 Adult	2	-	0.00361 mg/kg bw	0.00073 mg/kg bw	0.00434 mg/kg bw
Scenario 6 Child	2	-	0.00473 mg/kg bw	0.00184 mg/kg bw	0.00657 mg/kg bw

- **Combined scenarios**

Not relevant.

3.6.3.2 *Dietary exposure*

Table 57

Intended use(s) (critical application with regard to dietary exposure)	
Meta SPC	1, 2, 3, 4
Active substance(s) (a.s.)	iodine
Type of formulation	ready-to-use liquid solution
Substance(s) of concern	isotridecanol, ethoxylated, CAS-no. 69011-36-5 (meta SPC 2 and 4) decan-1-ol, ethoxylated, CAS-no. 26183-52-8 (meta SPC 2 and 4)
Field(s) of use	indoor and outdoor
Target organism(s)	bacteria and yeast
Application rate(s) and frequency	Biocidal products are used for post-milking disinfection of teats by manual dipping, foaming or spraying, semi-manual spraying or automated spraying application. The frequency of applications is 1 – 3 x /day. Solutions are concentrated 0.27 % a.s. for meta SPC 1 and 3 and with 0.312 % a.s. for meta SPC 2 and 4.
Category(ies) of users	professional
Waiting periods after treatment	none
Further information	/
Meta SPC	5
Active substance(s) (a.s.)	iodine
Type of formulation	soluble concentrate
Substance(s) of concern	- polyethylene glycol carboxymethyl dodecyl ether (laureth-11 carboxylic acid), CAS-no. 27306-90-7 - alcohols, C12-15-branched and linear, ethoxylated, propoxylated, CAS-no. 120313-48-6 - orthophosphoric acid, CAS-no. 7664-38-2
Field(s) of use	indoor
Target organism(s)	bacteria, yeast, viruses
Application rate(s) and frequency	Biocidal product is used for animal house disinfection by spraying with a diluted in-use concentration of 0.04 % a.s. and an application rate of 400 mL/m^2 (corresponding to 160 mg a.s./m^2)

Category(ies) of users	professional
Waiting periods after treatment	re-entry of animals after treated areas are dried
Further information	- biocidal product is intended to be used in pig and poultry stables - during the application, no animal should be present in the animal houses

List of scenarios

Table 58

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
1.	Animal husbandry	Post-milking teat disinfection by dipping, foaming or spraying	Livestock animals (cows, buffaloes, sheep and goats)
2.	Animal husbandry	Animal house disinfection by spraying	Livestock animals (pigs and poultry)

3.6.3.3 *Information of non-biocidal use of the active substance*

Table 59

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Veterinary use	Teat-disinfection for the prevention and control of mastitis.	Iodine is permitted as a pharmacologically active substance according to Commission Regulation (EU) No 37/2010 of 22 Dec. 2009. No MRLs are required for all food and food producing species.
2.	Food supplements	Supplementation of food, e.g. salt	Iodine may be used in the manufacture of food supplement according Directive 2002/46/EC. Iodine content of foods highly variable, richest sources are marine products, eggs and milk and iodised salt (10 - 75 mg iodine/kg fortified salt according to EFSA NDA Panel, 2014[9])

9 EFSA Scientific Opinion on Dietary Reference Values for iodine, 2014. EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), EFSA Journal 2014; 12(5):3660.

3.	Feed additives	Trace element for feeding stuffs	Maximum content for dairy cows and laying hens: 5 mg iodine/kg feeding stuff according Commission Regulation (EC) No 1459/2005. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) recommends the maximum iodine contents in complete feed be reduced for dairy cows/minor dairy ruminants to 2 mg iodine/kg and for laying hens to 3 mg iodine/kg (EFSA, 2013[10]).

3.6.3.4 *Estimating Livestock Exposure to Active Substances used in Biocidal Products*

- **Scenario [1]: Animal husbandry - post-milking teat disinfection**

Table 60

Description of Scenario [1]
The biocidal products of meta SPC 1, 2, 3 and 4 are applied as teat disinfection by dipping, foaming or spraying. The products contain up to 0.312 % (w/w) of active substance (a.s.). Contamination of food with iodine is possible via dermal uptake in livestock animals and subsequent transfer into edible tissues and milk and via direct contact of biocidal product with milk during the milking process. For tier 1 following two scenarios are estimated: - dermal exposure of livestock animals - direct transfer of residues into milk Since the spraying application leads to highest exposure of biocidal product in livestock animals, calculation for dermal uptake is done using the values for the spraying scenario. Default values are taken from Guidance Document (GD) for estimating livestock exposure to active substances used in biocidal products*. For tier 2 results of a study published by O`Brien (2013) on iodine residues in milk after disinfection of teats with a teat-spray containing 0.5 % iodine are taken into calculation. This is in line with the decisions for several ongoing Union authorisations for iodine-containing biocidal products that were made in the 2017 HH WG. Parameters and values for tier 1 and 2 are listed in the following table:

	Parameters / reference	Value
Tier 1:	max. concentration of product (C_prod)	0.312 % = 3120 mg/kg x 1.03 kg/L (density milk) = 3213.6 mg/L ≙ 3.2136 mg/ml

10 EFSA Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all species: calcium iodate anhydroused (coated granulated preparation), based on a dossier submitted by Doxal Italia S.p.A., EFSA Journal 2013; 11(3):3178.

	product volume on teats per milking for spraying application (V_prod)	20 mL/cow/milking
	body weight (bw) for dairy cows	650 kg
	Maximum post-milking applications/day (n)	3
	fraction of product remaining on teats (f_prod)	0.5
	daily milk yield of the dairy cow (V_milk)	15L/day
Tier 1 – A Dermal exposure	assuming 100 % dermal absorption and 0 % degradation of the a.s.	
Tier 1 - B Residues in milk	assuming 0 % dermal absorbtion and 0 % degradation of the a.s.	
Tier 2	For tier 2 the results of a teat-disinfection study reported by O`Brien (2013) [11] are taken into account. <u>Method:</u> Three groups of 10 Holstein cows were treated with either 0.5 % iodine post-milking spray, 0.5 % iodine pre- and post-milking spray and non-iodine post-milking spray. Cow milk samples were analysed for iodine concentration at the end of each treatment period. <u>Results:</u> Additional iodine residues in milk due to post-milking teat-disinfection for: - 2 x post-milkings/day - 3 x post-milkings/day (extrapolated) Control group	 244 µg iodine/kg milk 366 µg iodine/kg milk 217 µg iodine/kg milk
*Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products, Guidance on BPR Volume III Parts B+C Version 4.0,December 2017.		

[11] O`Brien, B., Gleeson, D. and Jordan, K. (2013): Iodine concentrations in milk. Irish Journal of Agricultural and Food Research 52: 209-216.

Table 61

External livestock exposure estimate for Scenario [1]	
For screening scenario external livestock exposure is estimated assuming that the entire amount of product applied to teats by spraying is carried over into the animal by dermal absorption. Screening 1 – A: estimation of screening scenario: *n* × *(V_prod* × *f_prod* × *C_prod)* ÷ *bw* Screening calculation is performed in order to compare result with the pre-defined threshold of concern (with trigger value of 0.004 mg/kg bw/d), as described in the GD for livestock exposure *.	
	External livestock exposure [mg a.s./kg bw/d]
1 – A: Screening/dermal exposure (for threemilkings/day)	0.11
Trigger exceeded?	yes
Conclusion: Because the trigger value for dermal exposure calculation is exceeded, further refinement is required.	
* Guidance on Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products, Guidance on BPR Volume III Parts B+C Version 4.0, December 2017.	

Table 62

Estimated residues in milk for Scenario [1]		
For tier 1 the following estimation is used to calculate the iodine contamination, assuming 100 % of the applied active substance is directly transferred into milk after 3 post-milking applications per day for worst-case assumption: Screening 1 – B: estimation of contamination during milking: $R_{milk} = n \times (V\_prod \times f\_prod \times C\_prod) \div V\_milk$ For tier 2 values for milk contamination were extrapolated from the teat disinfection study reported by O`Brien (2013), taking into account the average residue in milk after two post-milking treatments per day with a 0.5 % iodine-containing product: Linear extrapolation (calculations are included in chapter 4.3.7): Maximal additional residue value for a product with 0.5 % iodine = 244 µg/kg ≙ 251 µg/L - Extrapolated for a product with 0.312 % iodine / 2 post-milkings/day = 152 µg/kg x 1.03 kg/L (milk density) = 157 µg/L ≙ 0,16 mg/L - Extrapolated for a product with 0.312 % iodine/3 post-milkings/day = 228 µg/kg x 1.03 kg/L (milk density) = 235 µg/L ≙ 0.24 mg/L		
	Assumption	**Milk contamination [mg/L]**
Tier 1	100 % of applied biocidal product is transferred into milk (for 3 milkings/day)	3.6
Tier 2	Investigated additional iodine residue in milk (extrapolated from experimental data (for 3 milkings/day)	0.24

Table 63

Calculations for estimating worst-case consumer exposure (WCCE) - EU approach

At latest HH WG discussions in 2017, the following harmonised approach for Union authorisations was agreed for the assessment of iodine-content teat disinfection biocidal products:

- Worst-case consumer exposure (WCCE) should include following three calculations:
  1) exposure from teat treatment alone (for maximal 3 milkings/day)
  2) exposure from total milk intake (teat treatment + background from milk)
  3) exposure from total dietary intake (teat treatment + background from milk + dietary intake from other sources)
- As iodine background in milk the value 200 µg/L iodine based on monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) is considered to be acceptable.
- The Member States agreed to take the values from a UK study (UK retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008) for including iodine dietary intake from other sources than milk until newer data is available. The values 185 µg iodine/day for adults (referring to 70 kg bw) and 96 µg iodine/day for toddlers (referring to 12 kg bw) were agreed.
- Calculated iodine dietary intakes are to be compared to the upper intake level (UL) for adults (600 µg/day) and toddlers (200 µg/day)

Background	iodine in milk	200 µg/L
	iodine intake from other sources: adults toddlers	 185 µg/day 96 µg/day
Reference values	UL adults UL toddlers	600 µg iodine/day 200 µg iodine/day

For evaluating consumer exposures it was agreed at WG IV to use following EFSA PRIMo values (EFSA PRIMo revision 2, based on highest mean for Dutch population) for daily milk consumption:

- 0.45 L milk/day for adults (based on highest mean for Dutch population)
- 0.46 L milk/day for toddler (based on highest mean for French toddlers)

	Worst-case consumer exposures – EU approach*			
	Iodine exposure - adults (L/day)	**% UL**	**- Iodine exposure - toddlers (µg/day)**	**% UL**
1) teat treatment (for 3 post-milkings/day)	106	18	108	54
2) teat treatment + background from milk	196	33	200	100

3) teat treatment + background from milk + dietary intake from other sources	381	63	286	143
* calculations are included in chapter 4.3.7				

Conclusion: Following tier 2 EU approach WCCE shows exceedance of the UL for toddlers (143 % of UL) if adding iodine intake from teat disinfection treatment, highest level of iodine background in milk reported for Europe and iodine dietary intake from other sources reported for UK. When only the daily intake of iodine resulting from the worst-case proposed biocidal product use is estimated, 54 % of the UL is reached.

Table 64

Estimation of WCCE for Germany				
Data for the average iodine content of milk can highly vary the different European countries. The values range predominately from 100 to 200 µg iodine/L milk (Flachowsky et al., 2014)[12]. A recent study from Germany (Thuringia) with 135 samples of cow`s milk reports a mean iodine concentration of 122 µg iodine/L milk (Köhler et al., 2012)[13]. For the daily intake of iodine in Germany data from the National Nutrition Survey II (NVS II) [14] for adults and data from the VELS-study[15] for children is available. Following milk consumption is reported: - 0.9 L milk/day for adults - 0.3 L milk/day for children Taking the available data from Germany, results for WCCE are following:				
Worst-case consumer exposures - national approach (Germany)*				
	- Iodine exposure - adults (µg/day)	**% UL**	**- Iodine exposure - children (µg/day)**	**% UL**
1) teat treatment (for 3 post- milkings /day)	219	37	72	36
2) teat treatment + background from milk	333	55	110	55
3) teat treatment + background from milk + dietary intake from other sources	518	86	196	98
* calculations are included in chapter 4.3.7				
Conclusion: Following tier 2 approach for the estimation of the worst-case consumer exposure of the biocidal product based on national data shows no exceedance of the UL, neither for adults nor for toddlers.				

12 Flachowsky, G., Franke, K., Meyer, U., Leiterer, M., and Schöne, F. (2014): Review: Influencing factors on iodine content of cow milk. Eur J Nutr, 53, 351-365.

13 Köhler, M., Fechner, A., Leiterer, M., Sporl, K., Remer, T., Schafer, U., Jahreis, G. (2012): Iodine content in milk from German cows and in human milk: new monitoring study. Trace Elem Electrolytes 29(2):119-126.

14 German National Nutrition Survey II (2008). Max Rubner-Institut, Bundesforschungsinstitut für Ernährung und Lebensmittel:: https://www.bmel.de/SharedDocs/Downloads/Ernaehrung/NVS_Ergebnisbericht.pdf?__blob=publicationFile (Teil 1; date: 21.12.2016), https://www.bmel.de/SharedDocs/Downloads/Ernaehrung/NVS_ErgebnisberichtTeil2.pdf?__blob=publicationFile (Teil 2; date 21.12.2016)

15 Heseker, H., Oepping, A., Vohmann, C. (2003): Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln (VELS). Forschungsbericht der Universität Paderborn im Auftrag des Bundesministeriums für Verbraucherschutzm Ernährung und Landwirtschaft, Bonn.

Information about the daily intake of iodine in Germany is available from NVS II for adults and from the KiGGS study for children and adolescents[16]. Since iodine-containing products have been applied for many years in veterinary medicine as well as in biocidal products for disinfection of teats it can be concluded, that the data considers also the additional iodine residues in milk and other relevant edible animal tissues due to these applications. Taking into account from NVS II as worst case the value of 233 µg/kg for the daily iodine intake for adults (German men of 84.6 kg average body weight) and from the KiGGS data the value of 175,5 µg iodine intake/day (based on converted urinary iodine concentration), the following consumer exposure estimate could be taken into consideration:

	Iodine exposure µg./d	**% UL**
Total consumer exposure – adults (men)	233	38
Total consumer exposure – children and adolescents	175.5	88

Further information and considerations

Additional refinement proposals for tier 2 were made by applicant but not adopted for the assessment. These decisions are in line with the agreements of the HH WG that have been reached for the ongoing Union authorisations for iodine-containing teat disinfection biocidal products:

Applicant stated that DRA can be refined by taking into account that milk from cows treated with iodine based teat-disinfectant is always pooled with milk from herds which have not received iodine-based teat-disinfection. According to applicant market penetration for iodine-based teat-disinfectants was estimated to be below 50 % by Iodine Registration Group (IRG) members. We do not share this assumption, because dairy milk often comes from large-scale agricultural enterprises where animals usually are treated with the same product. Therefore a 50 % dilution of the consumed milk cannot be accepted as sufficiently justified.

A further refinement takes into account iodine loss by pasteurization. Due to an EFSA report (2013)17 milk pasteurization results in an approximate iodine concentration reduction of at least 27 %. However, further investigations show that this factor can highly vary. In the review of Flachowsky et al. (2014)18 the decrease of the iodine concentrations in raw milk after pasteurization can vary between 21.2 % and 53.1 %. On the other hand Aumount et al. (1986)[19] did not find any impact of pasteurization on iodine concentration in milk. Nazeri et al. (2015)[20] found out, that iodine concentration is not decreased during the process of sterilization, but is decreased during the pasteurization process. Both, Flachowsky and Nazeri, explained the iodine losses during treatment with the sublimation characteristic of the element, because more than 90 % of iodine in milk is inorganic. Our conclusion is that a defined value for iodine loss in milk due to milk processing procedures cannot be exactly determined based on available data and further investigations seem to be necessary. Therefore a 27 % reduction of calculated iodine concentration for the estimation of consumer exposure cannot be accepted.

16 Thamm, M., Ellert, U., Thierfelder, W. Liesenkötter, K.-P., and Völzke, H. (2007): Jodvesorgung in Deutschland. Ergebnisse des Jodmonitorings im Kinder- und Jugendgesundheitssurvey (KiGGS). Bundesgesundheitsblatt- Gesundheitsforschung – Gesundheitsschutz, 50:744-749.

17 see above

18 see above

19 Aumont, G., Le Querrec, F., Lamand, M., and Tressol, J.C. (1987): Iodine Content of Dairy Milk in France in 1983 and 1984. J Food Prot, 50 (6), 490-493.

20 Nazeri, P., Norouzian, M.A., Mirmiran, P., Hedayati, M., and Azizi, F. (2015): Heating Process in Pateurization and not in Sterilization Decreases the Iodine Concentration of Milk. Int J Endocrinol Metab, 13 (4), 27995, 1-4.

Conclusion on Scenario [1]

Following tier 2 EU approach the estimation of the worst-case consumer exposure of the biocidal product shows exceedance of the UL for toddlers (143 % of UL). The evaluation was carried out according to the decisions of the latest HH WGs in 2017 made for the ongoing Union authorisations for iodine-containing teat disinfection biocidal products. The calculation includes iodine intake from teat disinfection treatment, highest level of iodine background in milk reported for Europe and iodine dietary intake from other sources reported for UK.

However, a closer look at the existing data for the evaluation of teat-disinfection applications and the resulting additional iodine residues in milk shows high variability of the values. Flachowski et al. (2014)[21] reported in their review an average iodine concentration in milk between 50 - 60 µg/L, if products contain 3 - 5 g/l available iodine and are used for dipping after milking. The authors mentioned that the results also vary from no additional amounts up to more than 100 µg additional iodine/L. Thus it can be assumed that the results of the study from O'Brien (2013), which was the basis of the present assessment (tier 2), represent a worst-case.
Furthermore, considering data based on national surveys for iodine background in milk and milk consumption in WCCE calculations, the results show for three milkings/day no exceedance of the UL, neither for children nor for adults. If German iodine consumption data are taken into consideration, which also include the consumption of milk and iodised salt, evaluation shows a result of 38 % UL for adults (men) and 88 % UL for children and adolescents.

21 see above

- **Scenario [2]: Animal husbandry – animal house disinfection**

Table 65

Tier 1: Description of Scenario [2]		
The biocidal product is applied as a manual spray for disinfection of animal houses of pigs and poultry with a diluted in-use concentration of 0.04 % a.s. and an application rate of 400 mL/m^2 (corresponding to 160 mg a.s./m^2). During the application, no animals are present. After the application, the animal houses are left to dry before animal re-entry. Default values are taken from Guidance Document (GD) on Estimating Livestock Exposure to Active Substances used in Biocidal Products *.		
	Parameters	**Value**
Screening	Application rate (appl_rate)	160 mg/m^2
	Wall and floor area per stable (a_stable)	Fattening pigs: 970 m^2 Breeding pigs: 1160 m^2 Laying hens (free range): 2030 m^2 Broiler chickens (free range): 1600 m^2
	Number of animals per stable (n)	Fattening pigs: 400 Breeding pigs: 132 Laying hens (free range): 10000 Broiler chickens (free range): 20000
	Body weights (bw)	Fattening pigs: 100 kg Breeding pigs: 260 kg Laying hens: 1.9 kg Broiler chickens: 1.7 kg
Realistic worst-case estimate: oral exposure through licking of surface	Emission factor for spraying (fraction of spray product emitted to whole treated surface) (ef_spray)	0.85
	Tongue surface area (pigs) (a_t)	0.008 m^2
	Licks per day (l_d)	10
Realistic worst-case estimate: oral exposure through uptake of contaminated feed	Exposed feed surface (a_f)	1.2 m^2 (fattening pigs) 2.8 m^2 (breeding pigs) 0.01 m^2 (laying hens, broiler chickens)
	Emission factor for spraying (fraction of spray product emitted to floor during surface treatment) (ef_spray_fl)	0.85
Realistic worst-case estimate: dermal exposure	Body surface area in contact with surface (a_bs)	Fattening pigs = 0.45 m^2 Breeding pigs = 0.84 m^2
* Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products, Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017.		

Calculations for estimating livestock exposure for Scenario [2]

Table 66

Tier 1: External livestock exposure estimate for Scenario [2]				
The screening scenario describes the disinfection of stables for breeding pigs, fattening pigs, laying hens and broiler chickens. For screening external livestock exposure is estimated assuming that the entire amount applied to disinfect animal houses is carried over into the animal. - Calculation of screening scenario: $Exp_{ext} = appl\_rate \times a\_stable \div n \div bw$ For realistic worst-case estimate oral and dermal scenarios for fattening and breeding pigs are calculated. Because laying hens and broiler chickens do not show licking or rubbing behaviours, only the scenario "Oral exposure through uptake of contaminated feed" is taken into account. - Calculation of oral exposure through licking of surfaces: $Exp_{ext} = appl\_rate \times ef\_spray \times a\_t \times 10 \div bw$ - Calculation of oral exposure through uptake of contaminated feed: $Exp_{ext} = appl\_rate \times ef\_spray\_fl \times a\_f \div bw$ - Calculation of dermal exposure through rubbing against surfaces: $Exp_{ext} = appl\_rate \times ef\_spray \times a\_bs \div bw$ Screening and realistic worst-case estimate are performed in order to compare results with the pre-defined threshold of concern (with trigger value of 0.004 mg/kg bw/d), as described in the DRAWG Draft GD for livestock*.				
	Fattening pigs [mg a.s./kg bw/d]	**Breeding pigs [mg a.s./kg bw/d]**	**Laying hens [mg a.s./kg bw/d]**	**Broiler chickens [mg a.s./kg bw/d]**
Screening [mg a.s./kg bw/d]	3.88	5.41	17.10	7.53
Trigger exceeded?	**Yes**	**Yes**	**Yes**	**Yes**
Realistic worst-case estimate: oral exposure-licking surfaces	0.1088	0.0418	-	-
Realistic worst-case estimate: oral exposure-uptake contaminated feed	1.632	1.4646	0.7158	0.8

Realistic worst-case estimate: dermal exposure	0.612	0.439	-	-
Realistic worst-case estimate: total exposure	2.3528	1.945	0.7158	0.8
Trigger exceeded?	**Yes**	**Yes**	**Yes**	**Yes**
Conclusion: Because the trigger value for calculation of the screening and the realistic worst-case estimate scenarios is exceeded, further refinement is required.				
* Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products; Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017.				

Table 67

Calculations for estimating worst-case consumer exposure (WCCE) – EU approach (EMA food basket)

Worst-case consumer exposure (WCCE) calculation is performed with values from the EMA food basket for adults[22].

EMA food basket: 0.5 kg edible tissues (meat, kidney and liver)/day
0.1 kg eggs/day

Calculation of Worst-case consumer exposure:

WCCE = ($R_{esidues}$ x edible tissues consumption/day) + ($R_{esidues}$ x egg consumption)

$R_{esidues}$ = residues in animal edible tissues (here: total exposure from realistic worst-case estimate)

a) Disinfection of animal house for pigs and hens:

WCCE (meat, kidney and liver): 2.3528 mg/kg bw/day x 0.5 kg meat/day = 1.18 mg/day

WCCE (eggs: 0.7158 mg/kg bw/day) x 0.1 kg eggs /day = 0.07 mg/day

Total WCCE (meat, kidney, liver and eggs) = 1.25 mg/day = 1250 µg/day

b) Disinfection of animal house for pigs and hens – troughs for pigs excluded:

WCCE (meat, kidney and liver): 0.7208 mg/kg bw/day x 0.5 kg meat/day = 0.3604 mg/day

WCCE (eggs): 0.7158 mg/kg bw/day) = x 0.1 kg eggs/day = 0.07 mg/day

Total WCCE (meat, kidney, liver and eggs) = 0.4304 mg/day = 430 µg/day

Reference value: UL (toddler) = 600 µg/day

	Iodine exposure (µg/d)	**% UL**

22 The food basket is mainly reflecting the dietary pattern of adults, which differs from the children's pattern. This difference is not fully covered by the food basket, but the EMA considered that the system in place for the establishment of MRLs for milk is adequate also for children (EMEA/CVMP/391/02-FINAL-corrigendum November 2002).

WCCE – adults	**1250**	**208**
WCCE – adults (troughs excluded)	**430**	**72**
Conclusion: Following realistic worst-case approaches, the WCCE exceeds the UL for adults. If the disinfection of pig troughs is excluded by appropriate risk mitigation measures, UL will not be exceeded.		

Table 68

Calculations for estimating worst-case consumer exposure (WCCE) - EU approach (PRIMO data)
Worst-case consumer exposure calculation is performed with highest value of total exposure for realistic worst-case estimate for pigs and laying hens using the PRIMO data (rev. 2) for the chronic consumption of swine (1011000) and eggs chicken (1030010) added together: Consumption data from PRIMO (rev. 2): - Adults: 78.3 g/day for swine (LT adults, 70 kg) and 53 g/day for eggs chicken (SE general, 60 kg) - Children: 53.7 g/day for swine (ES child, 34.5 kg) and 25 g/day for eggs chicken (ES child, 34.5 kg) *Calculation of Worst-case consumer exposure:* *WCCE = ($R_{esidues}$ x edible tissues consumption) + ($R_{esidues}$ x egg consumption)* *$R_{esidues}$ = residues in animal edible tissues (here total exposure from realistic worst-case estimate)* *Iodine exposure: total exposure – fattening pig × swine consumption:* *Adults: 2.3528 mg/kg bw/day × 0.0783 kg/day = 0.184 mg/day ≙ 184 µg/day* *Children: 2.3528 mg/kg bw/day x 0.0537 kg/day = 0.1263 mg/day ≙ 126.3 µg/day* *Iodine exposure: total exposure – laying hens x egg consumption:* *Adults: 0.7158 mg/kg bw/day x 0.053 kg/day = 0.038 mg/day ≙ 38 µg/day* *Children: 0.7158 mg/kg bw/day × 0.025 kg/day = 0.018 mg/day ≙ 17.9 µg/day* *Total iodine exposure:* *Total iodine exposure (swine and eggs) – adults: 222 µg/day* *Total iodine exposure (swine and eggs) – children: 144.2 µg/day* Reference values: UL – adults = 600 µg/day UL – toddler = 200 µg/day

	Iodine exposure [µg/d]	**% UL**
WCCE – adults	**222**	**37**
WCCE – children	**144.2**	**72**

Conclusion: Following realistic worst-case approaches based on German consumption data, the WCCE does not exceed the UL, neither for adults nor for children.

Table 69

Calculations for estimating worst-case consumer exposure (WCCE) – national approach (Germany)
Worst-case consumer exposure calculation is performed with highest value of total exposure for realistic worst-case estimate for pigs and laying hens using the German consumption data from NVS II and VELS for the chronic consumption of swine (1010000) and eggs (chicken, 1030010) added together: Consumption data from NVS II and VELS: - German adults (76.37 kg): 93.58 g/day for swine and 22.55 g/day for eggs - German children (16.15 kg): 9.3 g/day for swine and 18 g/day for eggs *Calculation of Worst-case consumer exposure:* *WCCE = ($R_{esidues}$ x edible tissues consumption) + ($R_{esidues}$ x egg consumption)* *$R_{esidues}$ = residues in animal edible tissues (here total exposure from realistic worst-case)* *Iodine exposure: total exposure – fatteneing pigs x swine consumption* *Adults: 2.3528 mg/kg bw/day x 0.0938 kg/day = 0.221 mg/day ≙ 220.7 µg/day* *Children: 2.3528 mg/kg bw/day × 0.0093 kg/day = 0.022 mg/day ≙ 22 µg/day* *Iodine exposure: total exposure - laying hens × egg consumption* *Adults: 0.7158 mg/kg bw/day × 0.02255 kg/day = 0.0161 mg/day ≙ 16.1 µg/day* *Children: 0.7158 mg/kg bw/day x 0.018 kg/day = 0.0129 mg/day ≙ 12.9 µg/day* *Total iodine exposure:* *Total iodine exposure (swine and eggs) – adults: 236.8 µg/day* *Total iodine exposure (swine and eggs)– toddler: 34.9 µg/day* Reference values: UL – adults = 600 µg/day UL – children = 200 µg/day

	Iodine exposure [µg/d]	**% UL**
WCCE – adults	**236.8**	**39**
WCCE – children	**34.9**	**18**

Conclusion: Following realistic worst-case approaches based on German consumption data, the WCCE does not exceed the UL, neither for adults nor for children.

Conclusion on Scenario [2]:

Calculations for estimating worst-case consumer exposure (WCCE) were performed with values from the EMA food basket as well as with food consumption data provided by European Member States and collected for the calculation model PRIMO (Pesticide Residue Intake Model).

Based on the calculation with the food basket data - as it is recommended in the guidance on estimating livestock exposure - UL for adults (based on data which covers also the children consumption) is exceeded by 108 %. However, it is stated by the European Commission and EMA in 2005 that data from food basket represents high arbitrary daily consumption[23].

Calculating with PRIMO consumption values, which are closer to the real consumption, the WCCE does not exceed the UL, neither for adults nor for children. For adults, the estimated daily intake of iodine resulting from worst-case proposed biocidal product use is 37 % of the UL based on highest European consumers from PRIMO model and 39 % of the UL based on national data from Germany. For children, the estimated daily intake of iodine is 72 % based on PRIMO data and 18 % of UL based on data from Germany.

Because PRIMO values are also used for calculation of the consumer exposure from the use of the biocidal products for teat disinfection and have been agreed at HH WG IV 2017, it appears acceptable to consider the PRIMO data also for the final assessment of the risks from the use of the biocidal products for animal house disinfection. In conclusion, the use of the iodine-containing biocidal products of meta SPC 5 does not lead to an exceedance of the UL for adults and children if the performed calculations with the more realistic data from PRIMO are accepted.

3.6.3.5 *Estimating Livestock exposure to Substance of Concern used in Biocidal Products*

For the biocidal products of meta SPC 2 and 4 used for post-milking disinfection of teats and of meta SPC 5 used for disinfection of animal houses of pigs and poultry, following substances of concern (SoC) have to be considered:

Table 70

SPC	Substance(s) of concern	CAS No.	Classifi-	Qualitative assessment

23 European Commission and EMEA (2005): Notice to applicants and Guideline Veterinary medicindal products. Establishment of maximum residue limits (MRLs) for residues of veterinary medicinal products in foodstuffs of animal origin. (https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-8/pdf/vol8_10-2005_en.pdf; date: 26.11.2018)

No.			cation	
2, 4	Isotridecanol, ethoxylated	69011-36-5	Eye Dam. 1	No harmonised classification Water solubility: 44.03 mg/L Log Pow: 4.9 Vapour Pressure: < 5 Pa Substance induces local effects like eye damages. Generally such substances are not considered to be systemically available and no accumulation in animal tissue is expected.
2, 4	Decan-1-ol, ethoxylated	26183-52-8	Eye Dam. 1	No harmonised classification Substance induces local effects like eye damages. Generally such substances are not considered to be systemically available and no accumulation in animal tissue is expected.
5	Polyethylene glycol carboxymethyl dodecyl ether (laureth-11 carboxylic acid)	27306-90-7	Eye Dam. 1, Skin Irrit. 2	No harmonised classification Substance induces local effects like skin irritations and eye damages. Generally such substances are not considered to be systemically available and no accumulation into animal tissue is expected. As after application of biocidal product animal houses are left to dry before animal re-entry, inhalation exposure of livestock is not expected to be relevant.
5	Alcohols, C12-15-branched and linear, ethoxylated, propoxylated	120313-48-6	Skin Irrit. 2	No harmonised classification HERA, 2009[24]: Log Kow = 5.36 – 6.03 Substance induces local effects like skin irritation. According to the assessment of HERA (2009) regarding systemic toxicity, the use of alcohol ethoxylates in consumer products such as laundry and cleaning detergents does not raise any safety

[24] HERA, 2009: Human & Environmental Risk Assessment on ingredients of European household cleaning products – Alcohol Ethoxlates. Version 2.0. http://www.heraproject.com/files/34-f-09%20hera%20ae%20report%20version%202%20-%203%20sept%2009.pdf (date: 08.12.2016).

				concerns. Furthermore substances are generally highly efficiently metabolized and there is limited potential for accumulation. As after application of biocidal product animal houses are left to dry before animal re-entry, inhalation exposure of livestock is not expected to be relevant.
5	Orthophosphoric acid	7664-38-2	Skin Corr. 1B	REACH: Water solubility: 850 g/l (20°C, pH 0.5) Log Pow: no data Vapour pressure = 80 Pa (25°C) Substance induces local effects like skin corrosion. It is not considered to be systemically available after dermal or oral exposure and therefore no accumulation into animal tissues is expected. Due to the low vapour pressure inhalation exposure is not relevant.

Conclusion

Livestock exposure from the SoC of meta SPCs 2, 4 and 5 is not considered to be relevant for consumer

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

Not applicable. Exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPD. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.

3.6.3.7 *Summary of exposure assessment*

For professional use please refer to Table 50, Table 52, Table 53 and Table 54.
For general public please refer to Table 56

3.6.4 Risk characterisation for human health

3.6.4.1 *Reference values to be used in Risk Characterisation*

Table 71

	Value	Source
AEL (long-term, medium-term, acute) = Upper Intake Level (UL)	Europe 600 µg/d (0.01 mg/kg bw/d)	Assessment-Report (RMS SE (13 December 2013))
ACE Inhalative	0.1 ppm/mg/m^3	Assessment-Report (RMS SE (13 December 2013))
ADI	0.01 mg iodine/kg	Assessment-Report (RMS SE (13 December 2013))
Oral absorption	> 90 %	Assessment-Report (RMS SE (13 December 2013))
Dermal absorption	11.3 – 12 %	Assessment-Report (RMS SE (13 December 2013))
	75 %	Default value for untested products/formulations with a.s. concentration < 5 % (EFSA Journal 2012;10(4):2665)

3.6.4.2 *Maximum residue limits or equivalent*

Table 72

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRLs	Commission Regulation (EU) No 37/2010	Food of animal origin	No MRLs are required for all food producing species.

3.6.4.3 *Risk for industrial users*

No industrial applications are intended.

3.6.4.4 *Risk for professional users*

The BPF comprises five meta SPCs. An overview of the applications applied for the five meta SPCs is given in Table 44. All members of the BPF contain iodine (CAS No.: 7553-56-2) as active substance

Exposure of professional users to biocidal products generally takes place via the inhalation and/or dermal route and is usually assessed by means of external inhalation and/or dermal exposure values. For many substances (both active substances and substances of concern) external reference values such as occupational exposure limits (OELs) are available. By contrast, internal reference values (AELs) normally exist for active substances only. Therefore, external reference values will preferably be the basis for the risk characterisation of biocidal products as chemical mixtures. In case only internal reference values are available, they will be converted to external reference values in order to allow for a comparison with external exposure values.
For information: using the internal reference value for the active substance iodine in the occupational risk assessment yields the same results.

3.6.4.4.1 Risk for professional users for meta SPC 1

General considerations

The occupational risk assessment for biocidal products covered by meta SPC 1 takes into account systemic and local effects of the active substance iodine. The risk assessment is carried out for a concentration of 0.312 % iodine which is applicable for the biocidal products covered by meta SPC 2 and therefore represents worst case for meta SPC 1 (0.27% iodine).

- **Systemic effects**

Iodine is an essential dietary trace element for mammals being required for the synthesis of the thyroid hormones. Both iodine deficiency as well as excess iodine can impair thyroid homeostasis/thyroid hormone levels. The primary toxic effect of the active substance iodine is an inhibitory effect on the thyroid secretion. As reference value the Upper Intake Level (UL) of 600 µg iodine/day for adults is used (corresponding to 0.01 mg/kg bw/day). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to iodine resulting from use of the biocidal products covered by meta SPC 1.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to iodine from the biocidal products covered by meta SPC 1, inhalation and dermal exposure to iodine is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (=UL: 0.01 mg/kg bw/d) of iodine is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of iodine, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of iodine (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of iodine (in mg/kg bw/d) / %-dermal absorption x 100%.

By this means, RV_{inhal} equivalent to 0.06 mg/m^3 and RV_{derm} equivalent to 0.08 mg/kg bw/d are calculated for iodine.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance iodine.

Dermal absorption rate

A value of 12 % is used as dermal absorption rate for dilutions of iodine. This value is taken from the assessment report (SE (2013)).

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Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance iodine resulting from use of the biocidal products covered by meta SPC 1 are determined according to the following equations:

RQ_{inhal} = inhalation exposure to iodine (in mg/m^3) / RV_{inhal} of iodine (in mg/m^3).

RQ_{derm} = dermal exposure to iodine (in mg/kg bw/d) / RV_{derm} of iodine (in mg/kg bw/d).

Dermal exposure to iodine given in mg/kg bw/d is calculated from dermal exposure to iodine given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 73 gives a detailed overview of the risk assessment results referring to the active substance iodine for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 73. However, the underlying calculations are based on unrounded exposure values.

A risk for professional users referring to the active substance iodine resulting from the use of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 73, the scenarios ‘teat disinfection – dipping and

foaming', 'teat disinfection – manual spraying by electronic sprayer', and 'teat disinfection - spraying by robot' yield RI of less than 1 already in TIER 1. By contrast, the RI of the scenario 'teat disinfection – manual spraying by trigger sprayer' exceeds the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenarios. However, when risk mitigation measures are implemented the risk characterisation result consistently yield RI of less than 1 in TIER 2.

Table 73: Overview of detailed systemic risk assessment results referring to the active substance iodine for the biocidal products covered by meta SPC 1

Scenario		inhalation external			dermal external				RI	Accept-able
		potential / actual exposure	RV_{inhal}	RQ_{inhal}	potential/actual exposure		RV_{derm}	RQ_{derm}		
		mg/m^3	mg/m^3		mg/person	mg/kg bw/d	mg/kg bw/d			
Teat disinfection - dipping or foaming	Tier 1	$8.25x10^{-3}$	0.06	0.14	0.67	0.01	0.08	0.13	0.27	yes
	Tier 2	$8.25x10^{-3}$	0.06	0.14	0.07	$1.12x10^{-3}$	0.08	0.01	0.15	yes
Teat disinfection - manual spraying by trigger sprayer	Tier 1	0.01	0.06	0.17	4.73	0.08	0.08	0.95	1.24	no
	Tier 2	0.01	0.06	0.17	1.25	0.02	0.08	0.25	0.42	yes
Teat disinfection - manual spraying by electronic sprayer	Tier 1	0.01	0.06	0.17	4.10	0.07	0.08	0.82	0.99	yes
	Tier 2	0.01	0.06	0.17	1.19	0.02	0.08	0.24	0.41	yes
Teat disinfection - spraying by robot	Tier 1	not expected			0.02	$2.93x10^{-4}$	0.08	$3.51x10^{-3}$	$3.51x10^{-3}$	yes
	Tier 2	not expected			$1.76x10^{-3}$	$2.93x10^{-5}$	0.08	$3.51x10^{-4}$	$3.51x10^{-4}$	yes

RV_{inhal}: reference value for the inhalation route
RQ_{inhal}: risk quotient for the inhalation route
RV_{derm}: reference value for the dermal route
RQ_{derm}: risk quotient for the dermal route
RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the a.s. iodine via the inhalation and dermal route, a risk for professional users resulting from the intended uses 'teat disinfection - dipping or foaming', 'teat disinfection - manual spraying by trigger sprayer', 'teat disinfection – manual spraying by electronic sprayer' and 'teat disinfection - spraying by robot' with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 at least after TIER 2 consideration. Regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the provisions described in chapter 2.3 of this PAR.

- **Local effects**

The local toxicity profile of the a.s. iodine is also considered. Iodine has irritating properties (skin, eye and respiratory tract). However the content in the formulation does not lead to classification of the biocidal products covered by meta SPC 1. Since there is an $AEC_{inhalative}$ (respiratory tract irritation) available a quantitative risk characterisation for professional user is carried out.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to iodine from the biocidal products covered by meta SPC 1, inhalation exposure to iodine is assessed. For this, the local reference value $AEC_{inhalative}$ (1 mg/m^3) of iodine is used as external inhalation reference value and directly compared with airborne concentrations of iodine.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the active substance iodine resulting from use of the biocidal products covered by meta SPC 1 is determined according to the equation:

RI = inhalation exposure to iodine (in mg/m^3) / $AEC_{inhalative}$ of iodine (in mg/m^3).

Table 74 gives a detailed overview of the local risk assessment results for inhalation route referring to the active substance iodine for the biocidal products covered by meta SPC 1. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 74. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the active substance iodine resulting from the use of the biocidal products covered by meta SPC 1 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 74, the scenarios 'teat disinfection - dipping or foaming', 'teat disinfection - manual spraying by trigger sprayer', and 'teat disinfection – manual spraying by electronic sprayer' yields a RI of far less than 1 after TIER 1 consideration. For scenario 'teat disinfection - spraying by robot' inhalation exposure is not expected.

Table 74: Overview of detailed local risk assessment results for inhalation route referring to the active substance iodine for the biocidal products covered by meta SPC 1

Scenario		external inhalation		RI	Accept-able
		potential/ actual exposure mg/m³	external reference value $AEC_{inhalative}$ mg/m³		
Teat disinfection - dipping or foaming	Tier 1	$8.25x10^{-3}$	1.00	$8.25x10^{-3}$	**yes**
Teat disinfection - manual spraying by trigger sprayer	Tier 1	0.01	1.00	0.01	**yes**
Teat disinfection - manual spraying by electronic sprayer	Tier 1	0.01	1.00	0.01	**yes**
Teat disinfection - spraying by robot	Tier 1	not expected			**yes**

RI: substance specific risk index

Conclusion

Based on the local risk assessment of the a.s. iodine via the inhalation route, a risk for professional users resulting from the intended uses ('teat disinfection - dipping or foaming', 'teat disinfection - manual spraying by trigger sprayer', 'teat disinfection – manual spraying by electronic sprayer', 'teat disinfection - spraying by robot') with the biocidal products covered by meta SPC 1 is unlikely since the respective risk characterisation consistently yields risk indices of far less than 1 after TIER 1 consideration.

Overall Conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 1 is unlikely for the intended uses 'teat disinfection - dipping or foaming', 'teat disinfection - manual spraying by trigger sprayer', 'teat disinfection – mnaula spraying by electronic sprayer' and 'teat disinfection - spraying by robot'. Risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 1.
For a component (UVCB substance) contained in the biocidal products covered by meta SPC 1 the composition is not fully known. The risk assessment is based on the assumption that the biocidal products covered by meta SPC 1 contain no further substances relevant for evaluation.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.4.2 Risk for professional users for meta SPC 2

General considerations

The following substances are identified as substances of concern (SoCs) regarding biocidal products covered by meta SPC 2 based on self-classification with H318 (Causes serious eye damage) in the safety data sheet submitted by the applicant: isotridecanol, ethoxylated (CAS No.: 69011-36-5) and decan-1-ol, ethoxylated (CAS-No.: 26183-52-8).

The occupational risk assessment for biocidal products covered by meta SPC 2 takes into account systemic and local effects of the active substance iodine as well as local effects of the SoCs.

- **Systemic effects**

The systemic risk assessment for professional users for biocidal products of meta SPC 2 is covered by the risk assessment as presented in section 3.6.4.4.1 for biocidal products of meta SPC 1. For details refer to this section.

- **Local effects**

The local toxicity profiles of the a.s. iodine as well as the SoCs isotridecanol, ethoxylated (CAS No.: 69011-36-5) and decan-1-ol, ethoxylated (CAS-No.: 26183-52-8) are considered. These substances of concern contribute to the classification of the biocidal products covered by meta SPC 2 with H319 (Causes serious eye irritation). Therefore a qualitative risk characterisation for the professional user is performed. Since there is an $AEC_{inhalative}$ (respiratory tract irritation) for the active substance iodine available a quantitative risk characterisation for professional user is carried out.

Quantitative local risk characterisation

The quantitative local risk assessment for professional users for biocidal products of meta SPC 2 is covered by the risk assessment as presented in section 3.6.4.4.1 for biocidal products of meta SPC 1. For details refer to this section.

Qualitative local risk characterisation

The SoC isotridecanol, ethoxylated and decan-1-ol, ethoxylated contribute to the classification of the biocidal product with H319 (Causes serious eye irritation) and is therefore assigned in hazard classification band A according to the Guidance on substances of concern (Annex A to ECHA Guidance Vol III Part B, version 2). In this guidance is stated that for these SoCs appropriate risk mitigation measures in the form of the precautionary (P)-statements should be applied. It is assumed that the application of the precautionary statements associated with the concerned hazard statement H319 and the provisions described in chapter 2.4 are sufficient to minimize the risk for professional users.

Conclusion

Based on the local risk assessment of the active substance iodine via the inhalation route, a risk for professional users resulting from the intended uses (‘teat disinfection - dipping or foaming’, ‘teat disinfection - manual spraying by trigger sprayer’, ‘teat disinfection – manual spraying by electronic sprayer’, ‘teat disinfection - spraying by robot’) with the biocidal products covered by meta SPC 2 is unlikely since the respective risk characterisation consistently yields risk indices of far less than 1 after TIER 1 consideration. Based on the P-statements associated with the concerned H-statement and the provisions described in chapter 2.4 of this PAR a risk for professional users resulting from exposure to the SoCs isotridecanol, ethoxylated and decan-1-ol, ethoxylated is unlikely.

Overall Conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 2 is unlikely for the intended uses ‘teat disinfection - dipping or foaming’, ‘teat disinfection - manual spraying by trigger sprayer’, ‘teat disinfection – manual spraying by electronic sprayer’ and ‘teat disinfection - spraying by robot’. Risk mitigation measures described in chapter 2 have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 2.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.4.3 Risk for professional users for meta SPC 3

The risk assessment for professional users for biocidal products of meta SPC 3 is covered by the risk assessment for the intended use 'teat disinfection - dipping or foaming' as presented in section 3.6.4.4.1 for biocidal products of meta SPC 1. For details refer to this section.

3.6.4.4.4 Risk for professional users for meta SPC 4

The risk assessment for professional users for biocidal products of meta SPC 4 is covered by the risk assessment for the intended use 'teat disinfection - dipping or foaming' as presented in section 3.6.4.4.2 for biocidal products of meta SPC 2. For details refer to this section.

3.6.4.4.5 Risk for professional users for meta SPC 5

General considerations

The following substances are identified as SoCs regarding biocidal products covered by meta SPC 5 based on classification according to Annex VI of Regulation (EC) No 1272/2008 with H314 (Causes severe skin burns and eye damage): orthophosphoric acid (CAS No: 7664-38-2) and with H319 (Causes serious eye irritation): 2-(2-butoxyethoxy)ethanol (CAS No: 112-34-5) as well as based on self-classification in the safety data sheet submitted by the applicant with H318 (Causes serious eye damage): polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7) and with H315 (Causes skin irritation): polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7) and alcohols, C12-15 branched and linear, ethoxylated, propoxylated (CAS No: 120313-48-6).

The occupational risk assessment for biocidal products covered by meta SPC 5 takes into account systemic and local effects of the active substance iodine as well as local effects of the SoCs.

- **Systemic effects**

Iodine is an essential dietary trace element for mammals being required for the synthesis of the thyroid hormones. Both iodine deficiency as well as excess iodine can impair thyroid homeostasis/thyroid hormone levels. The primary toxic effect of the active substance iodine is an inhibitory effect on the thyroid secretion. As reference value the Upper Intake Level (UL) of 600 µg iodine/day for adults is used (corresponding to 0.01 mg/kg bw/day). The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to iodine resulting from use of the biocidal products covered by meta SPC 5.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from exposure of professional users to iodine from the biocidal products covered by meta SPC 5, inhalation and dermal exposure to iodine is assessed. For this, the systemic reference value $AEL_{long\text{-}term}$ (=UL: 0.01 mg/kg bw/d) of iodine is used. Since this systemic reference value is to be compared with external inhalation and dermal exposure concentrations of iodine, the corresponding $AEL_{long\text{-}term}$ is converted to an external inhalation reference value (RV_{inhal}) and an external dermal reference value (RV_{derm}) according to the following equations:

RV_{inhal} (in mg/m^3) = $AEL_{long\text{-}term}$ of iodine (in mg/kg bw/d) x 60 kg / 10 m^3 x100 % / %-inhalation absorption

RV_{derm} (in mg/kg bw/d) = $AEL_{long\text{-}term}$ of iodine (in mg/kg bw/d) / %-dermal absorption x 100%.

By this means, RV_{inhal} equivalent to 0.06 mg/m^3 and RV_{derm} equivalent to 0.08 mg/kg bw/d are calculated for iodine.

Absorption by inhalation

As default inhalation absorption of 100 % is assumed for the active substance iodine.

Dermal absorption rate

A value of 12 % is used as dermal absorption rate for dilutions of iodine. This value is taken from the assessment report (SE (2013)).

Calculation of risk quotients (RQ) and substance specific risk index (RI)

The risk quotient for the inhalation route (RQ_{inhal}) and dermal route (RQ_{derm}) referring to the active substance iodine resulting from use of the biocidal products covered by meta SPC 5 are determined according to the following equations:

RQ_{inhal} = inhalation exposure to iodine (in mg/m^3) / RV_{inhal} of iodine (in mg/m^3).

RQ_{derm} = dermal exposure to iodine (in mg/kg bw/d) / RV_{derm} of iodine (in mg/kg bw/d).

Dermal exposure to iodine given in mg/kg bw/d is calculated from dermal exposure to iodine given in mg/person through division by 60 kg/person.

The summation of RQ_{inhal} and RQ_{derm} for a substance within a scenario gives the corresponding substance specific risk index (RI). Table 75 gives a detailed overview of the risk assessment results referring to the active substance iodine for the biocidal products covered by meta SPC 5. It is noted that for clarity reasons exposure values, risk quotients and total risk indices are rounded to two decimal places in Table 75. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the active substance iodine resulting from the use of the biocidal products covered by meta SPC 5 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 75, the RI of the scenario ‘disinfection of animal houses – manual spraying (2 %)’ exceeds the value of 1 after TIER 1 consideration. This means that after TIER 1 consideration a risk for professional users cannot be excluded for the aforementioned scenario. However, when risk mitigation measures are implemented the risk characterisation result consistently yield RI of less than 1 in TIER 2.

Table 75: Overview of detailed systemic risk assessment results referring to the active substance iodine for the biocidal products covered by meta SPC 5

Scenario		inhalation external			dermal external				RI	Accep-table
		potential/actual exposure mg/m³	RV_{inhal} mg/m³	RQ_{inhal}	potential/actual exposure mg/person	mg/kg bw/d	RV_{derm} mg/kg bw/d	RQ_{derm}		
Disinfection of animal houses - manual spraying (2 %)	Tier 1	0.03	0.06	0.54	35.72	0.60	0.08	7.14	7.69	no
	Tier 2	0.03	0.06	0.54	2.17	0.04	0.08	0.43	0.98	yes

RV_{inhal}: reference value for the inhalation route
RQ_{inhal}: risk quotient for the inhalation route
RV_{derm}: reference value for the dermal route
RQ_{derm}: risk quotient for the dermal route
RI: substance specific risk index

Conclusion

Based on the systemic risk assessment of the active substance iodine via the inhalation and dermal route, a risk for professional users resulting from the intended use 'disinfection of animal houses – manual spraying (2 %)' with the biocidal products covered by meta SPC 5 is unlikely since the respective risk characterisation consistently yields risk indices of less than 1 after TIER 2 consideration. Regarding occupational safety, there are no objections against the aforementioned intended uses taking into account the provisions described in chapter 2.3 of this PAR.

- **Local effects**

The local toxicity profiles of the a.s. iodine as well as the SoCs orthophosphoric acid (CAS No: 7664-38-2), 2-(2-butoxyethoxy)ethanol (CAS No: 112-34-5) polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7) and alcohols, C12-15 branched and linear, ethoxylated, propoxylated (CAS No: 120313-48-6) are considered. These SoCs contribute to the classification of the biocidal products covered by meta SPC 5 with H315 (Causes skin irritation) and H318 (Causes serious eyedamage). Therefore a qualitative risk characterisation for the professional user is performed. Since there is an $AEC_{inhalative}$ (respiratory tract irritation) for the a.s. iodine as well as an Indicative Occupational Exposure Limit Value (IOELV) and furthermore a German OEL for the SoCs orthophosphoric acid and 2-(2-butoxyethoxy)ethanol available a quantitative risk characterisation for professional user is carried out.

Quantitative local risk characterisation

Details of risk characterisation for the active substance iodine

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to iodine from the biocidal products covered by meta SPC 5, inhalation exposure to iodine is assessed. For this, the local reference value $AEC_{inhalative}$ (1 mg/m^3) of iodine is used as external inhalation reference value and directly compared with airborne concentrations of iodine.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the active substance iodine resulting from use of the biocidal products covered by meta SPC 5 is determined according to the equation:

$$RI = \text{inhalation exposure to iodine (in } mg/m^3) \text{ / } AEC_{inhalative} \text{ of iodine (in } mg/m^3).$$

Table 76 gives a detailed overview of the local risk assessment results for inhalation route referring to the active substance iodine for the biocidal products covered by meta SPC 5. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 76. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the active substance iodine resulting from the use of the biocidal products covered by meta SPC 5 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 76, the scenario 'Disinfection of animal houses - manual spraying (2 %)' yields a RI of far less than 1 after TIER 1 consideration.

Table 76: Overview of detailed local risk assessment results for inhalation route referring to the active substance iodine for the biocidal products covered by meta SPC 5

Scenario		external inhalation		RI	acceptable
		potential/ actual exposure mg/m³	external reference value $AEC_{inhalative}$ mg/m³		
Disinfection of animal house - manual spraying	Tier 1	0.03	1.00	0.03	**yes**

RI: substance specific risk index

Details of risk characterisation for the SoC orthophosphoric acid

For the SoC orthophosphoric acid local irritation is considered as critical effect with respect to inhalation exposure. A quantitative risk characterisation for professional user is carried out since there is a German OEL for orthophosphoric acid available.

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to orthophosphoric acid from the biocidal products covered by meta SPC 5, inhalation exposure to orthophosphoric acid is assessed. For this, the German OEL (2 mg/m³, 8 h TWA) for aerosol of orthophosphoric acid is used as external inhalation reference value and directly compared with airborne concentrations of orthophosphoric acid.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the SoC orthophosphoric acid resulting from use of the biocidal products covered by meta SPC 5 is determined according to the equation:

> RI = inhalation exposure to orthophosphoric acid (in mg/m³) / German OEL of orthophosphoric acid (in mg/m³).

Table 77 gives a detailed overview of the local risk assessment results for inhalation route referring to the substance of concern orthophosphoric acid for the biocidal products covered by meta SPC 5. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 77. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the substance of concern orthophosphoric acid resulting from the use of the biocidal products covered by meta SPC 5 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 77, the scenario 'Disinfection of animal houses - manual spraying (2 %)' yields a RI of far less than 1 after TIER 1 consideration.

Table 77: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern orthophosphoric acid for the biocidal products covered by meta SPC 5

Scenario		external inhalation		RI	acceptable
		potential/ actual exposure mg/m³	external reference value German OEL mg/m³		
Disinfection of animal house - manual spraying	Tier 1	0.05	2.00	0.03	**yes**

RI: substance specific risk index

Details of risk characterisation for the SoC 2-(2-butoxyethoxy)ethanol

For the SoC 2-(2-butoxyethoxy)ethanol local irritation is considered as critical effect with respect to inhalation exposure. A quantitative risk characterisation for professional user is carried out since there is a German OEL for 2-(2-butoxyethoxy)ethanol acid available.

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to 2-(2-butoxyethoxy)ethanol from the biocidal products covered by meta SPC 5, inhalation exposure to 2-(2-butoxyethoxy)ethanol is assessed. For this, the German OEL (67 mg/m³, 8 h TWA) for 2-(2-butoxyethoxy)ethanol is used as external inhalation reference value and directly compared with airborne concentrations of 2-(2-butoxyethoxy)ethanol.

Calculation of substance specific risk index (RI)

The substance specific risk index (RI) referring to the SoC 2-(2-butoxyethoxy)ethanol resulting from use of the biocidal products covered by meta SPC 5 is determined according to the equation:

RI = inhalation exposure to 2-(2-butoxyethoxy)ethanol (in mg/m³) / German OEL of 2-(2-butoxyethoxy)ethanol (in mg/m³).

Table 78 gives a detailed overview of the local risk assessment results for inhalation route referring to the substance of concern 2-(2-butoxyethoxy)ethanol for the biocidal products covered by meta SPC 5. It is noted that for clarity reasons exposure values and risk indices are rounded to two decimal places in Table 78. However, the underlying calculations are based on unrounded exposure values.
A risk for professional users referring to the SoC 2-(2-butoxyethoxy)ethanol resulting from the use of the biocidal products covered by meta SPC 5 is unlikely if the risk characterisation for each scenario yields a risk index (RI) of less than 1. As shown in Table 78, the scenario 'Disinfection of animal houses - manual spraying (2 %)' yields a RI of far less than 1 after TIER 1 consideration.

Table 78: Overview of detailed local risk assessment results for inhalation route referring to the substance of concern 2-(2-butoxyethoxy)ethanol for the biocidal products covered by meta SPC 5

Scenario		external inhalation		RI	acceptable
		potential/ actual exposure mg/m^3	external reference value German OEL mg/m^3		
Disinfection of animal house - manual spraying	Tier 1	0.04	67.00	5.79x10^{-4}	**yes**

RI: substance specific risk index

Qualitative local risk characterisation

The SoCs orthophosphoric acid (CAS No: 7664-38-2), 2-(2-butoxyethoxy)ethanol (CAS No: 112-34-5), polyethylene glycol carboxymethyl dodecyl ether (CAS No: 27306-90-7) and alcohols, C12-15 branched and linear, ethoxylated, propoxylated (CAS No: 120313-48-6) contribute to the classification of the biocidal products covered by meta SPC 5 with H315 (Causes skin irritation) and H318 (Causes serious eyedamage) and are therefore assigned in hazard classification band A according to the Guidance on substances of concern (SoC) (Annex A to ECHA Guidance Vol III Part B, version 2). In this guidance is stated that for these SoCs a qualitative exposure and risk assessment to determine whether precautionary (P)-statements associated with concerned hazard (H)-statement are sufficient or whether other risk mitigation measures should be applied. It is assumed that the application of the precautionary statements associated with the concerned hazard statement H318 and the relating provisions are sufficient to minimize the risk for professional users.

Conclusion

Based on the local risk assessment of the a.s. iodine as wells as the substances of concern orthophosphoric acid and 2-(2-butoxyethoxy)ethanol via the inhalation route, a risk for professional users resulting from the intended use (‘disinfection of animal houses – manual spraying (2 %)) with the biocidal products covered by meta SPC 5 is unlikely since the respective risk characterisation consistently yields risk indices of far less than 1 after TIER 1 consideration. Based on the P-statements associated with the concerned H-statements and the relating provisions a risk for professional users resulting from exposure to the SoCs orthophosphoric acid, 2-(2-butoxyethoxy)ethanol, polyethylene glycol carboxymethyl dodecyl ether and alcohols, C12-15 branched and linear, ethoxylated, propoxylated is unlikely.

Overall Conclusion

In summary, a risk for professional users resulting from the use of the biocidal products covered by meta SPC 5 is unlikely for the intended use ‘disinfection of animal houses – manual spraying (2 %)’. Risk mitigation measures have to be taken into account in order to ensure safe use of the biocidal products covered by meta SPC 5.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.5 *Risk for non-professional users*

No non-professional applications are intended.

3.6.4.6 *Risk for the general public*

Table 79: Systemic effects (only for meta SPC 5)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Secondary exposure after manual spraying of animal houses, Scenario 5, adults	1	0.03	0.01	0.00789	79	yes
Secondary exposure after manual spraying of animal houses, Scenario 5, children	1	0.03	0.01	0.01195	120	no
Secondary exposure after manual spraying of animal houses, Scenario 5, adults	2	0.03	0.01	0.00434	43	yes
Secondary exposure after manual spraying of animal houses, Scenario 5, children	2	0.03	0.01	0.00657	66	yes

Identification of SoCs is based on local effects only. Hence, a risk characterisation for systemic effects of SoCs is not required.

- **Local effects**

Local effects related to the active substance or substances of concern are not expected. The concentrated biocidal product is classified as eye and skin-irritating. However, the in-use-dilution would

not require any classification. Hence, it is expected that the concentration of residues on surfaces is below any level of concern.

Conclusion

In the absence of more reliable parameters, the assessment of this scenario is based on worst-case-assumptions. In addition, the corresponding reference value is considered very conservative for acute exposure.
Based on the human exposure and risk assessment a health risk was not identified for the general public entering animal houses after treatment if the surface is dried (Meta-SPC 5). Thus, in this context further risk mitigation measures to protect the general public are not necessary.

The general public, particularly children, has normally no access to animal houses due to hygienic and safety reasons. This might be different in small farms, where the family and guests lives nearby the animal houses. In this case the users of the biocidal products (all-Meta-SPC) have to be advised to keep the biocidal product out of reach of children to avoid unintended exposure.

3.6.4.7 *Risk for consumers via residues in food*

The risk for consumers via residues in food is evaluated for the two main representative dietary exposure scenarios (see also chapter “Dietary exposure”):

In Scenario [1] the risk for animal livestock through post-milking teat disinfection by spraying is assessed. As a result, the estimated worst-case consumer exposure (WCCE) based on the approach agreed in the EU (EU approach) is in most calculated cases below 100 % of the UL, but exceeds the UL for toddlers (143 % of UL) when European iodine background in milk and iodine intake from other sources are included into calculation. . If only the biocidal product intended use is considered without taking into account the background levels and other sources, all results are below the UL.However, considering data from national surveys for iodine background in milk and milk consumption of German adults and children in the assessment, no exceedance of the UL was determined. Furthermore, the evaluation of NVS II and KiGGS data for iodine intake, which also includes the consumption of milk and iodised salt, shows also results for consumer exposure below the UL.
Therefore, we conclude that a risk for consumer health from the intended use of the biocidal products of meta SPC 1, 2, 3 and 4 is not expected.
Nevertheless, taking into account the different possible sources of iodine intake, it is important to manage the overall dietary iodine intake by an integrated approach which concerns the different relevant regulatory areas (such as veterinary use, animal feed etc.). This has also been discussed at the latest BPC meetings in 2017.

In Scenario [2] the risk for livestock animals through animal house disinfection is calculated for the use of the iodine-containing biocidal product of meta SPC 5. The resulting WCCE does not exceed the UL, - neither for adults nor for children - when calculating with PRIMO consumption data (“EU approach”).. It is also assumed that livestock exposure from the SoC of meta SPC 5 is not considered to be relevant for consumer health. In summary regarding consumer health protection, there are no objections against the intended use of the iodine-containing products of meta SPC 5.

Note:

As a result of the WG discussions in 2017 on Union authorisations for iodine containing teat disinfectants it was agreed not to approach EMA with regard to MRL setting for iodine. However, some Member States indicated that this should be reconsidered during active substance renewal.

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

Not relevant.

3.6.4.9 *Summary of risk characterisation*

3.6.4.9.1 Summary of risk characterisation for professional user

For professional user please refer to Table 73 - Table 78.

3.6.4.9.2 Summary of risk characterisation for indirect exposure

Table 80

Scenario, Tier	**Relevant reference value**	**Estimated uptake** mg/kg bw/d	**Estimated uptake/reference value** (%)	**Acceptable** (yes/no)
Scenario 6, adults, Tier 1 (only for Meta-SPC 5)	0.01	0.00789 mg/kg bw	423	Yes
Scenario 6, children, Tier 1 (only for Meta-SPC 5)	0.01	0.01195 mg/kg bw	570	No
Scenario 6, adults; Tier 2 (only for Meta-SPC 5)	0.01	0.00434 mg/kg bw	233	Yes
Scenario 6, children, Tier 2 (only for Meta-SPC 5)	0.01	0.00657 mg/kg bw	313	Yes

Based on the human exposure and risk assessment no health risk was identified for the general public entering animal houses after treatment. Thus, further risk mitigation measures to protect the general public are not necessary..

3.7 Risk assessment for animal health

Livestock animals come in contact to iodine if biocidal products of this family are applied as intended. Cows are exposed to iodine from biocidal products of the meta SPC 1 to 4 used for teat disinfection Pigs and poultry are exposed to iodine from biocidal products of meta SPC 5 used for animal housing disinfection.
Exposure of cows, fattening pigs, breeding pigs, laying hens, broiler chickens was assessed for dietary exposure assessment (section 3.6.3.4) and represents also the worst case for other animals with respect to animal health. Systemic exposure values calculated in this section are used for a Tier 1 approach. In the absence of animal-specific reference values, the AEL/UIL (upper intake levels) derived for human health risk assessment are applied in Tier 1. Comparing the AEL/UIL to the exposure levels estimated in section 3.6.3.4 a health risk for these domestic animals cannot be excluded.

Table 81 Risk characterisation for animal health, Tier 1

	Realistic worst-case estimate: total exposure [mg a.s./kg bw/d]	**AEL/UIL [mg a.s./kg bw/d]**	**Exposure/UIL [%]**
Cows	0.096	0.01	960
Fattening pigs	0.932	0.01	9320
Breeding pigs	0.6703	0.01	6703
Laying hens	0.0926	0.01	926
Broiler chickens	0.1035	0.01	1035

The use of the human UIL is questionable for domestic animals and might be over-protective. According to the Commission implementing Regulation (EU) 2015/861 the maximum content of iodine in animal food shall not exceed 5 mg/kg feed (water content 12 %) for cows and laying hens and not 10 mg/kg feed (water content 12 %) for pigs and broiler chicken. It can be assumed that feeding stuffs, which fulfil the criteria of this regulation, can be considered as safe for the corresponding animals. Based on the body weight and the food intake of these animals as proposed in the DRAWG Draft Proposal Guidance in Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2) a maximum tolerable dose for these animals can be calculated for Tier 2.

Table 82 Risk characterisation for animal health, Tier 1, using maximum tolerable doses, calculated from maximum iodine levels in feed and animal`s feed intake

	Maximum con-tent in feed [mg/kg feed]	**Food intake [kg]**	**Body weight [kg]**	**Maximum tolera-ble dose (MTD) [mg a.s./kg bw/d]**	**Expoure/MTD [%]**
Cows	5	20	650	0.15	64
Fattening pigs	10	3	100	0.3	311

Breeding pigs	10	7.8	260	0.3	223
Laying hens	5	0.13	1.9	0.34	27
Broiler chickens	10	0.12	1.7	0.35	30

According to this Tier 2 approach exposure is acceptable for cows, laying hens and broiler chicken.

The exposure estimate according to the DRAWG Draft Proposal Guidance in Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products (CA-Dec10-Doc.6.2) is based on very conservative assumptions.

Dermal exposure: The transfer coefficient for surface-to-skin-contact is 100 %. The transfer coefficient for substances on glaze tiles to skin applied for human exposure assessment (Biocides Human Health Exposure Methodology, 2015) is 55 %. It is expected that this value is also applicable for pigs. In addition, the dermal absorption is set to 100 %. For human dermal absorption a default value of 75 % would be used. Considering the dermal absorption data available for human exposure assessment, which are considerably lower, and the similarity of human and pig skin, the default of 75 % is also applicable for pigs.

Oral exposure, eating of contaminated feed: This scenario is based on the assumption that the trough for the feed of one pig has a surface of 1.2 m^2 in case of fattening pigs and 2.8 m^2 in case of breeding pigs. Considering that the floor surface per each fattening pig and each breeding pig is 1.5 and 4.2 m^2, respectively, this value is considered very conservative. In addition, it is very unlikely that the whole amount in the trough and the surrounding floor is transferred to the feed. Hence, a reduction factor of 50 % is considered appropriate.

Oral exposure, licking surfaces: It is assumed that the surface of the whole tongue is 0.008 m^2. This surface is based on the surface of a calf tongue. The weight of a pig tongues is smaller than those of a calf tongue. In addition it is not expected that the whole surface of a tongue come into contact with a contaminated surface. Thus, a reduction factor of 50 % is considered appropriate.
Using these factors the Tier 2 exposure estimates for pigs as presented in section 3.6.3.4 results in the following values.

Table 83 Risk characterisation for animal health, Tier 2, for pigs using maximum tolerable doses, calculated from maximum iodine levels in feed and animal`s feed intake

	Fattening pigs [mg a.s./kg bw/d]	**Breeding pigs [mg a.s./kg bw/d]**
Realistic worst-case estimate: oral exposure- licking surfaces	0.0544	0.0209
Realistic worst-case estimate: oral exposure- uptake contaminated feed	0.1056	0.0948
Realistic worst-case estimate: dermal exposure	0.2525	0.1977

Realistic worst-case estimate: total exposure	0.4125	0.3134
Maximum tolerable dose (MTD) [mg a.s./kg bw/d]	0.3	0.3
Expoure/MTD [%]	138	105

Even after refinement the exposure estimates exceed the maximum tolerable dose derived from the maximum feed concentrations and the daily intakes. However, in the absence of a harmonised approach and the relatively small distance between the estimated and the tolerable dose it is not considered appropriate to ban the application in animal housings for pigs. However, as general rule the application of the biocidal products of this family has to be limited to cleaned and empty animal housings.

3.8 Risk assessment for the environment

3.8.1 General information

The BPF contains no substances of concern for the environment and there are no formulation additives contained in the products or properties of the formulation that are considered to affect the fate and the distribution of the a.s. in the environment. Consequently, the environmental risk assessment for the BPF is based on the information given in the Competent Authority Report (CAR) of the rapporteur member state (RMS) Sweden for the active substance (a.s.) iodine (CAS-No. 7553-56-2).
However, the BPF and the related products differ from the example biocidal product which was assessed in the CAR of the a.s.. Hence, the environmental exposure assessment described in the CAR could not be translated into the risk assessment for the BPF. Consequently, the environmental exposure assessment was adapted accordingly.

3.8.2 Effects assessment

For the environmental effects assessment no new studies were provided for the products that belong to the BPF. Thus, the effects assessment is based on the information given in the CAR for the a.s. iodine.

3.8.2.1 *Aquatic compartment (including sediment and STP)*

- **Acute aquatic toxicity**
  - **Surface water**

Table 84 Overview on studies on aquatic ecotoxicology of the a.s. iodine

Summary table for acute aquatic toxicity									
Guideline/Test method/GLP status/reliability	*Species*	*End point*	*Exposure*		*Results [L(E)C_{50}]*			*Remarks*	*Reference*
			Design	*Duration*	*Iodide*	*Iodate*	*Iodine*		
Fish									
Basically in agreement with OECD 203	*Oncorhynchus mykiss*	LC_{50}/ Acute toxicity	static	96 hours	*3780 mg/L*	*220 mg/L*	*1.67 mg/L*	-	A7.4.1.1 / 01
Invertebrates									
Basically in agreement with OECD	*Daphnia magna*	Acute toxicity	static	48 hours	*0.83 mg/L*	*58.5 mg/L*	*0.59 mg/L*	-	A7.4.1.2 / 01

202									
Algae (growth inhibition)									
					NOEC (Iodine)	*E_bC_{50} (Iodine)*	*E_rC_{50} (Iodine)*		
OECD 201 (1984)	*Desmo-desmus subspicatus*	Growth inhibition test	static	48 hours	*0.2 mg/L*	*0.62 mg/L*	*1.3 mg/L*	-	A7.4.1.3/01

The lowest EC_{50} of 0.59 mg/L for iodine was determined in the study on acute toxicity to Daphnia magna. Therefore, the $PNEC_{water}$-values for the relevant iodine species, i.e. iodine, iodate and iodide, were derived from the EC_{50}-values of 0.59, 58.5 and 0.83 mg iodine/L, respectively, observed in this study by applying an assessment factor 1000:

iodine: $PNEC(I_2)_{water}$ = 0. 59 µg iodine/L

iodate: $PNEC(IO_3^-)_{water}$ = 58.5 µg iodine/

iodide: $PNEC(I^-)_{water}$ = 0. 83 µg iodine/L

The natural background levels of iodine for freshwater are in a range of 0.5-20 µg/L (see section 3.8.3), and even if it is assumed that all iodine in freshwater would be present as iodate, the derived PNECs can be considered as very conservative and they appear to be an unrealistic worst case. Nevertheless in lack of more refined data, those PNECs will be used for the risk assessment.

- **Sediment**

The $PNEC_{sediment}$ values were calculated on the basis of the values for the $PNEC_{water}$, using the equilibrium partitioning method (EPM; According to equation 70 in the Guidance on the BPR, Vol. IV Part B, 2015). The $K_{susp\text{-}water}$ used in the calculation is 55.9 m^3/m^3.

iodine: $PNEC(I_2)_{sediment}$ = 29 µg iodine/kg

iodate: $PNEC(IO_3^-)_{sediment}$ = 2840 µg iodine/kg

iodide: $PNEC(I^-)_{sediment}$ = 43 µg iodine/kg

The natural background levels of iodine in freshwater sediments are typically 6 mg/kg. Thus, the derived values for $PNEC_{sediment}$ are also considered to be very conservative and may be regarded as an unrealistic worst case. Furthermore and due to the fact that both the PECs as wells as the PNECs are calculated using EPM, the PEC/PNEC-ratios for surface water and sediment in the environmental risk assessment will be similar. Thus, no environmental risk assessment for the sediment compartment will be performed.

- **STP**

The estimated EC_{50} value for respiration inhibition based on the water solubility of iodine is 290 mg/L. The assessment factor normally applied to this type of endpoint is 100 (Guidance on the BPR, Vol. IV Part B, 2015). Thus, the $PNEC_{STP\ microorganisms}$ is derived as:

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

3.8.2.2 *Terrestrial compartment (including groundwater)*

Table 85 Overview on studies on terrestrial ecotoxicology of the a.s. iodine

Summary table for terrestrial toxicity									
Guideline/Test method/GLP status/reliability	*Species*	*End point*	*Exposure*		*Results (nom. conc.)* mg/kg$_{dwt}$ (mg/kg$_{wwt}$)			*Remarks*	*Reference*
			Design	*Duration*	*NOEC*	*LOEC*	*EC/LC$_{50}$*		
Earthworm									
OECD 207 (1984)	*Eisenia fetida*	Mortality, change in biomass, abnormal behaviour or toxic symptoms	acute test in soil	14 days	*125 (93)*	-	*> 1000 (740)*	-	A7.5.1.2/01 A7.5.1/01
Terrestrial plants									
OECD 208 (2006)	*Avena sativa*	Seedling emergence and survival, shoot fresh weight, Phytotoxicity	seedling emergence & seedling growth test	*21 days*	*7.4 (6.5)*	*22.2 (19.5)*	*13.4 (11.8)*	-	A7.5.1.3/01 A7.5.1/01
	Allium cepa				*7.4*	*22.2*	*26.6 (23.4)*		
	Brassica napus				*7.4*	*22.2*	*22.1 (19.4)*		
	Helianthus annuus				*7.4*	*22.2*	*16.5 (14.5)*		
	Lycopersicon esculentum				*7.4*	*22.2*	*16.2 (14.3)*		
	Cucumis sativa				*7.4*	*22.2*	*14.2 (12.5)*		
Soil microorganisms									
OECD 217 (2000)	Soil micro-organisms	Respiration inhibition	Carbontransformationtest	28 days	*31.6 (26.5)*	-	*148.7 (125)*	-	A7.5.1.1/01
OECD 216 (2000)		Nitrate formation	Nitrogentransformationtest		*10 (8.4)*	-	*82.6 (69.4)*		A7.5.1/01

The effect concentration to be used for the PNEC-derivation was determined in the study on six non target plants, in which the lowest EC_{50} of 13.4 mg/kg$_{dw}$ (= 11.82 mg/kg$_{ww}$) was found for *Avena sativa* (shoot fresh weight). Therefore, the $PNEC_{soil}$ for iodine was derived on the basis of the EC_{50} for *A. sativa* by applying an assessment factor of 1000:

iodine: $PNEC(I_2)_{soil}$ = 0.0134 mg iodine/kg_{dw} = 11.8 µg/kg_{ww}

According to the CAR, the $PNEC_{soil}$ for iodate and iodide were calculated on the basis of the $PNEC_{water}$, using the equilibrium partitioning method (EPM) as described in equation 72 in the Guidance on the BPR, Vol. IV, Part B (2015):

$PNEC_{soil} = K_{soil\text{-}water}/RHO_{soil} * PNEC_{water} * 1000$

where

$K_{soil\text{-}water}$ = 8.9 m^3/m^3 (using the K_{psoil} of 5.8 cm^3/g)

RHO_{soil} = 1700 kg/m^3

$PNEC_{water}$ = 0.0585 mg iodine/L (IO_3^-) and 0.00083 mg iodine/kg (I^-)

iodate: $PNEC(IO_3^-)_{soil}$ = 304 µg iodine/kg

iodide: $PNEC(I^-)_{soil}$ = 4.3 µg iodine/kg

It should be noted that iodine is not a xenobiotic substance but is present in soil at natural background concentrations from 4 to 9 mg/kg soil (see section 3.8.3). Therefore, the application of an assessment factor of 1000 may be considered as an unrealistic worst case in the case of iodine.

3.8.2.3 *Atmosphere*

Considering the high background concentrations of iodine in air, emission to air resulting from the application of iodine as a disinfectant is not considered to be relevant. Also, iodine is assumed to transform into non-volatile iodide and iodate in the different compartments. Consequently, air is not an environmental compartment of concern and the potential effect on the ozone layer can be considered as negligible.

3.8.2.4 *Non-compartment specific effects*

As the amounts of iodine potentially released into the environment through biocidal uses are within the natural occurring background levels, there is no concern with regard to secondary poisoning. The low Kp-value is a second indicator of a low bioaccumulation potential.

3.8.2.5 *Summary of effects assessment*

Table 86 Summary of PNEC-values to be used in the environmental risk assessment

Summary table on calculated PNEC values		
Compartment	**Chemical speciation**	**PNEC**
Surface water	Iodine (I_2)	0.59 µg iodine/L
	Iodate (IO_3^-)	58.5 µg iodine/L
	Iodide (I^-)	0.83 µg iodine/L
STP	Iodine (I_2)	2.9 mg iodine/L
Soil	Iodine (I_2)	11.8 µg iodine/kg_{ww}
	Iodate (IO_3^-)	304 µg iodine/kg_{ww}
	Iodide (I^-)	4.3 µg iodine/kg_{ww}

3.8.3 Fate and behaviour

Detailed information on the fate and behaviour of iodine in the environment can be found in the CAR for the a.s. iodine. In the CAR it is stated that iodine and related iodine species are ubiquitously distributed and there is a natural cycle of iodine species in the environment (see Table 87). The natural background concentrations have to be taken into account for the evaluation of the environmental risk assessment.

Table 87 Background values likely to be encountered in soil, water and air.

Compartment	Background level (as iodine)	Reference	Discussed under CAR-section
Soil	Typically 0.5 - 20 mg/kg dw but with extremes up to 98 mg/kg Global mean value of 5 mg/kg	Overview: Johanson, 2000 (doc 781-002) Primary: Whitehead, 1984	A7.2.1/01-03
Groundwater	Mean concentration: 1 µg/l	Overview: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, 2004 (doc 581-009) Primary: Yuita, 1994a	A7.2.3.2
	Range: < 1-70 µg/l with extremes up to 400 µg/l	Overview: The British Geological Survey, 2000 (doc 792-015)	
Freshwater (river and lake)	0.5 - 20 µg/l	Overview: Christiansen and Carlsen, 1989 Primary: Whitehead, 1984	A7.1.2.2.1/01-02
Marine water	45 - 60 µg/L	Overview: U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, 2004 (doc 581-009) Primary: USNRC, 1979	A7.1.1.2.3/01-02
Rainwater	0.1-15 µg/l		-
Freshwater sediments	Typically: 6 mg/kg	Breheler and Fuge, 1974 and Mun and Bazilerich, 1964	A7.1.2.2.2
Marine sediments	Typically: 3-400 mg/kg	Whitehead, 1984	A7.1.1.2.3/01-02
Air	Atmosphere: 10-20 ng/m^3 Atmospheric concentration: over land: 2-14 ng/m^3	Overview: U.S. Department of Health and Human Services, Public Health	A7.3.2/01-02

Compartment	Background level (as iodine)	Reference	Discussed under CAR-section
	over oceans: 17-52 ng/m^3	Service, Agency for Toxic Substances and Disease Registry, 2004 (doc 581-009)	
	Marine air contains: 100 µg/l (may refer to local inhalable air)	Overview: Krone and Kirbach., 2007 (doc 781-004) Primary: FAO/WHO 2001	

With regard to the degradation of iodine, detailed information is given in the CAR. As stated in the CAR degradation is not applicable to an element, iodine may undergo different hydrolytic, photolytic and microbial transformation processes (i.e. speciation) in the different compartments. The presence of different forms of iodine is largely dependent on redox potential and pH. Iodide (I^-) and iodate (IO_3^-) are the dominant iodine species in soil. Iodate is the dominant chemical form of iodine in the soil solution under non-flooded conditions whilst under flooded conditions iodide is the dominant chemical form. In water, the prevalent iodine forms are iodide and iodate. In surface waters, the proportion of iodide to iodate will vary depending on microbial activity and the release of iodine species from terrestrial sources. Microbial action converts iodide to organic forms of iodine, primarily methyl iodide (CH_3I). Its high vapour pressure and limited solubility in water leads to volatilisation of methyl iodide from surface waters to the surrounding atmosphere. Also, microbial activity and photochemical reactions with iodide or iodate can lead to the formation of iodine, which evaporates to the atmosphere. At ordinary pressures and temperature, methyl iodide and iodine will exist, predominately in a free gaseous form, in air. Both iodine and methyl iodide undergo photochemical reactions to form iodine radicals, which can form a number of other iodine species.
Iodine as an element does not undergo biodegradation processes and although biotic transformation processes may be involved in the formation of the different iodine species no studies have been provided on the significance of such processes. It is likely that the magnitude of the natural occurrence of iodine species in the environment renders for example the formation of methyl iodide from biocidal use of iodine to be insignificant.
Hydrolysis of iodine takes place in a series of reactions and leads to the formation of iodide and iodate. Natural waters, particularly marine waters, contain iodine mainly in the form of iodide and iodate. Iodide (oxidation state -1) is the dominant iodine species in surface waters whilst iodate (oxidation state of iodine +5), the second most abundant form of iodine in aqueous systems, is found predominantly under alkaline and well oxidized conditions. In water, photolytic dissociation of methyl iodide can result in the formation of elemental iodine and inorganic iodine species. Also, photochemical production of iodine from a reaction between iodide and iodate upon irradiation with UV-light at sea level may occur. However, iodine production via this pathway may be regarded as insignificant.
Adsorption data for iodine has been acquired from an adsorption screening test according to OECD 106 and from publicly available information. A geometrical mean K_{OC} of 165.8 cm^3/g was calculated from the OECD 106 test in the CAR. However, the adsorption of iodine to soil is not only attributed to organic matter, even though this type of adsorption seems to be predominant at pH > 6. A different approach is therefore applied, i.e. to use measured partitioning coefficients K_d (or Kp_{comp} as given in the TGD) for soil and suspended matter directly. In conclusion, and in agreement with the statement in section 2.2.5.3 in the TGD that for ionic substances measured adsorption coefficients are needed, the solids-water adsorption coefficients to be used the environmental exposure calculations are Kp_{soil} = 5.8 cm^3/g and Kp_{susp} = 2.2 x 10^2 cm^3/g.

3.8.3.1 *Bioconcentration*

According to the CAR for the a.s., bioaccumulation/bioconcentration in the environment is considered to be not relevant for iodine.

3.8.4 Exposure assessment

3.8.4.1 *General information on meta SPC 1 to 4*

Products within the meta SPC 1 to 4 of the BPF are water-based RTU products containing iodine as active substance. The biocidal products are used for veterinary udder hygiene against bacteria and yeast in the following use areas:

Table 88: Meta SPC 1 - Intended uses

Assessed PT	PT 3
Assessed Intended uses	Use 1.1: Teat disinfection for lactating animals – manual dipping Use 1.2: Teat disinfection for lactating animals – manual foaming Use 1.3: Teat disinfection for lactating animals – manual spraying using a trigger spray Use 1.4: Teat disinfection for lactating animals – manual spraying using an electronic sprayer Use 1.5: Teat disinfection for lactating animals – automated spraying by robot
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011
Approach	Use 1.1: covered by Use 1.3 Use 1.2: covered by Use 1.3 Use 1.3: Average consumption based approach Use 1.4: covered by Use 1.3 Use 1.5: covered by Use 1.3
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier model are used because there is no need to perform a refined groundwater assessment.
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation: Yes (statement) Use: Yes Service life: No
Remarks	The maximum content is 0.27 % (w/w) a.s. in b.p. (= 2.7 g a.s./kg b.p. and corresponds to 2.7648 g a.s./L b.p.) and in chapter 2.3.4 the appropriate application rate(s) and frequency per intended use are given.

Table 89: Meta SPC 2 - Intended uses

Assessed PT	PT 3
Assessed Intended uses	Use 1.1: Teat disinfection for lactating animals – manual dipping Use 1.2: Teat disinfection for lactating animals – manual foaming Use 1.3: Teat disinfection for lactating animals – manual spraying using a trigger spray Use 1.4: Teat disinfection for lactating animals – manual spraying using an electronic sprayer Use 1.5: Teat disinfection for lactating animals – automated spraying by robot
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011
Approach	Use 1.1: covered by Use 1.3 Use 1.2: covered by Use 1.3 Use 1.3: Average consumption based approach Use 1.4: covered by Use 1.3 Use 1.5: covered by Use 1.3
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier models are used because there is no need to perform a refined groundwater assessment.
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation: Yes (statement) Use: Yes Service life: No
Remarks	The maximum content is 0.312 % (w/w)[8] a.s. in b.p. (= 3.12 g a.s./kg b.p. and corresponds to 3.186 g a.s./L b.p.) and in chapter 3.1 the appropriate application rate(s) and frequency per intended use are given.

Table 90: Meta SPC 3 - Intended uses

Assessed PT	PT 3
Assessed Intended uses	Use 1.1: Teat disinfection for lactating animals – manual dipping
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011
Approach	Use 1.1: Average consumption based approach
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier models are used because there is no need to perform a refined groundwater assessment.
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation: Yes (statement) Use: Yes Service life: No
Remarks	The maximum content is 0.27 % (w/w) a.s. in b.p. (= 2.7 g a.s./kg b.p. and corresponds to 2.835 g a.s./L b.p.) and in chapter 3.1 the appropriate application rate(s) and frequency per intended use are given.

Table 91: Meta SPC 4 - Intended uses

Assessed PT	PT 3
Assessed Intended uses	Use 1.1: Teat disinfection for lactating animals – manual dipping
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011
Approach	Use 1.1: Average consumption based approach
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier models are used because there is no need to perform a refined groundwater assessment.
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation: Yes (statement) Use: Yes Service life: No
Remarks	The maximum content is 0.312 % (w/w) [8] a.s. in b.p. (= 3.12 g a.s./kg b.p. and corresponds to 3.25728 g a.s./L b.p.) and in chapter 3.1 the appropriate application rate(s) and frequency per intended use are given.

Release Estimation for Production/Formulation of the Biocidal Product

The production of the 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, where relevant, air extraction to prevent emissions into the working environment.
Should spillages occur, they are taken up with inert material (sand, earth, chemical absorbent, etc.) and are collected in dedicated drums properly labelled. 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 (Information of the applicant).

Considerations for the Release Estimation for Professional Use

All intended uses within meta SPC 1 and 2 are comparable concerning the entry pathways into the environment, the used a.s. concentration in b.p. and the application frequency. The only difference is the application rate per use. The highest application rate of 15 mL per teat disinfection event (cows and buffaloes) is given for Use 1.3, Use 1.4 and Use 1.5 (spraying applications). Therefore, spraying (manual or automatic) results in the highest application rate per day and can be considered as worst-case covering also dipping and foaming and the RefMS decided to carry out all following calculations exemplary on base of Use 1.3.
In meta SPC 3 and 4 the application rate for Use 1.1 (manual dipping) is given of 10 mL per teat disinfection event (cows and buffaloes).
The following emission estimation for meta SPC 1 to 4 is performed based on the disinfection of teats of dairy cows. The maximum number of milkings per day is three. Even in the case of robotic milking, where individual cows may be milked five times per day, the average milking frequency per herd is always below three milkings per day. Consequently, emission estimation based on three milkings per day also covers disinfection in installation equipped with robotic milking systems. The BPF products within meta SPC 1 to 4 can also be used for disinfection of teats of buffaloes, sheep and goats.
Buffaloes (four teats) → equal to dairy cows. The application rate per animal and milking is equal to dairy cows. Since buffaloes are only milked two times a day, the iodine emission to the environment due to the use of teat disinfectants is lower than for a herd of dairy cows (assuming the same number of animals per herd).
Sheep and goats (two teats) → resulting in lower application rates per animal. These animals are only milked 1-2 times per day.
According to ENV 52 of TAB version 1.3 (ECHA, August 2017) the emission estimation for dairy cows are considered as worst-case with reference to teat disinfection and covers therefore also buffaloes, sheep and goats.

3.8.4.2 *General information on meta SPC 5*

Products within the meta SPC 5 of the BPF are soluble concentrates containing iodine as active substance. The biocidal products are used as disinfectants against bacteria and yeast in animal housings in the following use areas:

Table 92: Meta SPC 5 - Intended uses

Assessed PT	PT 3
Assessed Intended uses	Use 2.1: Disinfection of animal houses – manual spraying Assessed for the following different livestock animals: • Sows in individual pens (i1=4) • Sows in groups (i1=5) • Fattening pigs (i1=6) • Laying hens in battery cages (i1=7-10) • Laying hens in free range (i1=11, 13) • Broilers in free range (i1=12) • Parent broilers in free range (i1=14) • Parent Broilers in rearing (i1=15) • Turkeys (i1=16) • Ducks (i1=17) • Geese (i1=18)
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, EN 2011
Approach	Use 2.1: Average consumption based approach
Distribution in the environment	Calculated based on Guidance BPR IV ENV B (2015)
Groundwater simulation	No higher tier models are used because there is no need to perform a refined groundwater assessment.
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation Yes (statement) Use: Yes Service life: No
Remarks	The maximum content is 2 % (w/w) a.s. in b.p. (= 20.0 g a.s./kg b.p. and corresponds to 21.506 g a.s./L b.p.) and in chapter 3.1 the appropriate application rate(s) and frequency per intended use are given.

Release Estimation for Production/Formulation of the Biocidal Product

The production of Anti-Germ`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, where relevant, air extraction to prevent emissions into the working environment.
Should spillages occur, they are taken up with inert material (sand, earth, chemical absorbent, etc.) and are collected in dedicated drums properly labelled. 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 (Information of the applicant).

3.8.4.3 *Local emission estimation for relevant environmental compartments*

3.8.4.3.1 Meta SPC 1: Intended use 1.3 [Teat disinfection for lactating animals – manual spraying]

The emission estimation is based on Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.3 “Disinfection for veterinary hygiene: non-medical teat dips” (EN 2011). Therefore, two pathways into the environment are possible: emission to waste water and emission to slurry/ manure. The estimations are presented in the following tables.

Table 93: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Input parameters (ESD for PT3, 2011)

Parameter	Nomenclature	Value	Unit	Origin
Type of housing/manure storage (for application of the notification)	*cat-subcat (i1)*	i1= 1 (Dairy cows)	[-]	D
Type of biocide	*bioctype (i2)*	i2= 1 (Disinfectant)	[-]	D
Type of application	*appway (i3)*	i3= 1 (Spraying)	[-]	D
Relevant emission stream	*stream (i4)*	i4=1,2,3	[-]	P
Content of active ingredient in formulation (product)	*Fbioc*	2.7648	[$g.L^{-1}$]	S
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i3}$	0.015	[L]	S
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1	[-]	S
Fraction of active ingredient released	F_{stp} $F_{slurry/manure}$ F) F_{air} F_{teat}	0.5 0.5 0.0 0.5	[-]	D
Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	3	[-]	S
Number of days of lactation period (corresponds to number of emission days)	*Ndays-lact (= Temission)*	300	[d]	D
Number of disinfectant applications in one year (equals number of disinfectant applications on one lactation period)	*Napp-bioc*	900	[-]	O
Interval between two disinfectant applications (dipping events)	*Tbioc-int* B)	0.333	[d]	O
Number of manure applications for grassland (per year)	*Napp-grass*	4	[-]	D
Number of manure applications for agricultural land (per year)	*Napp-arab*	1	[-]	D
Manure application time interval for grassland	*Tgr-int*	53	[d]	D
Manure application time interval for arable land	*Tar-int*	212	[d]	S

Number of animals in housing	N_{animal}	100	[-]	D
Number of milk producing animal	$N_{mp\text{-}animal}$ G)	82	[-]	D
If nitrogen immission standards are applied: C)				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[kg.ha^{-1}]	D
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[kg.ha^{-1}]	D
Mixing depth with soil, grassland	$DEPTH_{grassland}$ D)	0.05	[m]	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$ D)	0.2	[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$ D,E)	1700	[kg.m^{-3}]	D

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10-1. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) The interval between the end of a lactation period and the beginning of a new one was not taken into account in the default value for Tbioc-int in order not to underestimate the emission into the manure and consequently the soil exposure.

C) According to ESD for PT 18 No. 14.

D) According to ESD for PT 18 No. 14.

E) According to Technical Guidance Document on Risk Assessment (TGD) in support of Directive 98/8/EC, Part II (EC 2003a).

F) Degradation of the active substance in slurry/manure is not considered in the first tier. A methodology to include biodegradation in manure and slurry as second-tier approach in the emission estimation is provided in the ESD for PT 18 No. 14.

G) According to TAB ENV 63 (v. 2.0, 2018)

Table 94: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Intermediate calculations (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	159	[-]	O
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	636	[-]	O
For grassland and arable land: If *Tbioc-int > Tgr/ar-int,* then *Napp-manure = 1* If *Tbioc-int < Tgr/ar-int,* then *Napp-manure = ROUND (Tgr/ar-int/Tbioc-int)* If *ROUND (Tgr/ar-int/Tbioc-int) > Napp-bioc,* then *Napp-manure = Napp-bioc* [A)] (ROUND is the sign for rounding off to a whole number)				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	4.147E-05	[kg]	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} \bullet Fbioc \bullet Vprod_{i1,i2,i3} \bullet F_{dil}$				
Amount of active ingredient in relevant stream *i4* after one application	*Qai*	1.700E-03	[kg]	O
Qai i1,i2,i3,i4 = Fstp or slurry/manure i1,i2,i3,i4 • Qai-prescr i1,i2,i3 • Nmp-animal1				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	0.270	[kg]	O
$Qai\text{-}grass_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{gr}$				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	1.081	[kg]	O
$Qai\text{-}arab_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{ar}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	1796.17	[kg]	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tgr\text{-}int_{i2}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	7184.68	[kg]	O
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tar\text{-}int_{i2}$				

A) according to OECD ESD Number 14, chapter 5.9 (2006)

Table 95: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Output parameters (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Soil exposure				
For stream *i4* =1 and 3				
Concentration of the biocide (active ingredient) in soil (mg.kg^{-1}) in the case of an immission standard for nitrogen and land application on grassland (**four** manure applications per year are considered)	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**0.03010**	[mg.kg^{-1}]	O
Concentration of the biocide (active ingredient) in soil (mg.kg^{-1}) in the case of an immission standard for nitrogen and land application on arable land (**one** manure applications per year is considered)	$PIECars\text{-}N_{i1,i2,i3,i4}$	**0.00753**	[mg.kg^{-1}]	O
STP				
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4}$ = $Elocal_{waste\ water}$	**5.11E-03**	[kg.d^{-1}]	O

3.8.4.3.2 Meta SPC 2: Intended use 1.3 [Teat disinfection for lactating animals – manual spraying]

The emission estimation is based on Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.3 “Disinfection for veterinary hygiene: non-medical teat dips” (EN 2011). Therefore, two pathways into the environment are possible: emission to waste water and emission to slurry/ manure. The estimations are presented in the following tables.

Table 96: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Input parameters (ESD for PT3, 2011)

Parameter	Nomenclature	Value	Unit	Origin
Type of housing/manure storage (for application of the notification)	*cat-subcat (i1)*	i1= 1 (Dairy cows)	[-]	D
Type of biocide	*bioctype (i2)*	i2= 1 (Disinfectant)	[-]	D
Type of application	*appway (i3)*	i3= 1 (Spraying)	[-]	D
Relevant emission stream	*stream (i4)*	i4=1,2,3	[-]	P
Content of active ingredient in formulation (product)	*Fbioc*	3.186	[g.L^{-1}]	S
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i3}$	0.015	[L]	S
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1	[-]	S
Fraction of active ingredient released	F_{stp} $F_{slurry/manure}$ F) F_{air} F_{teat}	0.5 0.5 0.0 0.5	[-]	D

Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	3	[-]	S
Number of days of lactation period (corresponds to number of emission days)	*Ndays-lact (= Temission)*	300	[d]	D
Number of disinfectant applications in one year (equals number of disinfectant applications on one lactation period)	*Napp-bioc*	900	[-]	O
Interval between two disinfectant applications (dipping events)	*Tbioc-int*[B)]	0.333	[d]	O
Number of manure applications for grassland (per year)	*Napp-grass*	4	[-]	D
Number of manure applications for agricultural land (per year)	*Napp-arab*	1	[-]	D
Manure application time interval for grassland	*Tgr-int*	53	[d]	D
Manure application time interval for arable land	*Tar-int*	212	[d]	S
Number of animals in housing	N_{animal}	100	[-]	D
Number of milk producing animal	$N_{mp\text{-}animal}$ [G)]	82	[-]	D
If nitrogen immission standards are applied: [C)]				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[kg.ha^{-1}]	D
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[kg.ha^{-1}]	D
Mixing depth with soil, grassland	$DEPTH_{grassland}$ [D)]	0.05	[m]	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$ [D)]	0.2	[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$ [D,E)]	1700	[kg.m^{-3}]	D

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10-1. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) The interval between the end of a lactation period and the beginning of a new one was not taken into account in the default value for Tbioc-int in order not to underestimate the emission into the manure and consequently the soil exposure.

C) According to ESD for PT 18 No. 14.

D) According to ESD for PT 18 No. 14.

E) According to Technical Guidance Document on Risk Assessment (TGD) in support of Directive 98/8/EC, Part II (EC 2003a).

F) Degradation of the active substance in slurry/manure is not considered in the first tier. A methodology to include biodegradation in manure and slurry as second-tier approach in the emission estimation is provided in the ESD for PT 18 No. 14.

G) According to TAB ENV 63 (v. 2.0, 2018)

Table 97: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Intermediate calculations (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	159	[-]	O
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	639	[-]	O
For grassland and arable land: If *Tbioc-int > Tgr/ar-int,* then *Napp-manure = 1* If *Tbioc-int < Tgr/ar-int,* then *Napp-manure = ROUND (Tgr/ar-int/Tbioc-int)* If *ROUND (Tgr/ar-int/Tbioc-int) > Napp-bioc,* then *Napp-manure = Napp-bioc* [A)] (ROUND is the sign for rounding off to a whole number)				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	4.779E-05	[kg]	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} \bullet Fbioc \bullet Vprod_{i1,i2,i3} \bullet F_{dil}$				
Amount of active ingredient in relevant stream *i4* after one application	*Qai*	1.959E-03	[kg]	O
Qai i1,i2,i3,i4 = Fstp or slurry/manure i1,i2,i3,i4 • Qai-prescr i1,i2,i3 • Nmp-animal1				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	0.312	[kg]	O
$Qai\text{-}grass_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{gr}$				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	1.246	[kg]	O
$Qai\text{-}arab_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{ar}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	1796.17	[kg]	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tgr\text{-}int_{i2}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	7184.68	[kg]	O
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tar\text{-}int_{i2}$				

A) according to OECD ESD Number 14, chapter 5.9 (2006)

Table 98: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Output parameters (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Soil exposure				
For stream *i4* =1 and 3				
Concentration of the biocide (active ingredient) in soil ($mg.kg^{-1}$) in the case of an immission standard for nitrogen and land application on grassland (**four** manure applications per year are considered)	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**0.03469**	[$mg.kg^{-1}$]	O
Concentration of the biocide (active ingredient) in soil ($mg.kg^{-1}$) in the case of an immission standard for nitrogen and land application on arable land (**one** manure applications per year is considered)	$PIECars\text{-}N_{i1,i2,i3,i4}$	**0.00867**	[$mg.kg^{-1}$]	O
STP				
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4}$ = $Elocal_{waste\ water}$	**5.89E-03**	[$kg.d^{-1}$]	O

3.8.4.3.3 Meta SPC 3: Intended use 1.1 [Teat disinfection for lactating animals – manual dipping]

The emission estimation is based on Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.3 “Disinfection for veterinary hygiene: non-medical teat dips” (EN 2011). Therefore, two pathways into the environment are possible: emission to waste water and emission to slurry/ manure. The estimations are presented in the following tables.

Table 99: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Input parameters (ESD for PT3, 2011)

Parameter	Nomenclature	Value	Unit	Origin
Type of housing/manure storage (for application of the notification)	*cat-subcat (i1)*	i1= 1 (Dairy cows)	[-]	D
Type of biocide	*bioctype (i2)*	i2= 1 (Disinfectant)	[-]	D
Type of application	*appway (i3)*	i3= 2 (Dipping)	[-]	D
Relevant emission stream	*stream (i4)*	i4=1,2,3	[-]	P
Content of active ingredient in formulation (product)	*Fbioc*	2.835	[$g.L^{-1}$]	S
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i3}$	0.010	[L]	S
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1	[-]	S
Fraction of active ingredient released	F_{stp} $F_{slurry/manure}$ F) F_{air} F_{teat}	0.5 0.5 0.0 0.5	[-]	D

Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	3	[-]	S
Number of days of lactation period (corresponds to number of emission days)	*Ndays-lact (= Temission)*	300	[d]	D
Number of disinfectant applications in one year (equals number of disinfectant applications on one lactation period)	*Napp-bioc*	900	[-]	O
Interval between two disinfectant applications (dipping events)	*Tbioc-int*[B)]	0.333	[d]	O
Number of manure applications for grassland (per year)	*Napp-grass*	4	[-]	D
Number of manure applications for agricultural land (per year)	*Napp-arab*	1	[-]	D
Manure application time interval for grassland	*Tgr-int*	53	[d]	D
Manure application time interval for arable land	*Tar-int*	212	[d]	S
Number of animals in housing	N_{animal}	100	[-]	D
Number of milk producing animal	$N_{mp\text{-}animal}$ [G)]	82	[-]	D
If nitrogen immission standards are applied: [C)]				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[$kg.ha^{-1}$]	D
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[$kg.ha^{-1}$]	D
Mixing depth with soil, grassland	$DEPTH_{grassland}$ [D)]	0.05	[m]	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$ [D)]	0.2	[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$ [D,E)]	1700	[$kg.m^{-3}$]	D

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10-1. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) The interval between the end of a lactation period and the beginning of a new one was not taken into account in the default value for Tbioc-int in order not to underestimate the emission into the manure and consequently the soil exposure.

C) According to ESD for PT 18 No. 14.

D) According to ESD for PT 18 No. 14.

E) According to Technical Guidance Document on Risk Assessment (TGD) in support of Directive 98/8/EC, Part II (EC 2003a).

F) Degradation of the active substance in slurry/manure is not considered in the first tier. A methodology to include biodegradation in manure and slurry as second-tier approach in the emission estimation is provided in the ESD for PT 18 No. 14.

G) According to TAB ENV 63 (v. 2.0, 2018)

Table 100: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Intermediate calculations (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	159	[-]	O
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	636	[-]	O
For grassland and arable land: If *Tbioc-int > Tgr/ar-int,* then *Napp-manure = 1* If *Tbioc-int < Tgr/ar-int,* then *Napp-manure = ROUND (Tgr/ar-int/Tbioc-int)* If *ROUND (Tgr/ar-int/Tbioc-int) > Napp-bioc,* then *Napp-manure = Napp-bioc* [A)] (ROUND is the sign for rounding off to a whole number)				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	2.835E-05	[kg]	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} \bullet Fbioc \bullet Vprod_{i1,i2,i3} \bullet F_{dil}$				
Amount of active ingredient in relevant stream *i4* after one application	*Qai*	1.162E-03	[kg]	O
Qai i1,i2,i3,i4 = Fstp or slurry/manure i1,i2,i3,i4 • Qai-prescr i1,i2,i3 • Nmp-animal1				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	0.185	[kg]	O
$Qai\text{-}grass_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{gr}$				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	0.739	[kg]	O
$Qai\text{-}arab_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{ar}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	1796.17	[kg]	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tgr\text{-}int_{i2}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	7184.68	[kg]	O
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tar\text{-}int_{i2}$				

A) according to OECD ESD Number 14, chapter 5.9 (2006)

Table 101: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Output parameters (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Soil exposure				
For stream *i4* =1 and 3				
Concentration of the biocide (active ingredient) in soil ($mg.kg^{-1}$) in the case of an immission standard for nitrogen and land application on grassland (**four** manure applications per year are considered)	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**0.02058**	[$mg.kg^{-1}$]	O
Concentration of the biocide (active ingredient) in soil ($mg.kg^{-1}$) in the case of an immission standard for nitrogen and land application on arable land (**one** manure applications per year is considered)	$PIECars\text{-}N_{i1,i2,i3,i4}$	**0.00515**	[$mg.kg^{-1}$]	O
STP				
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4}$ = $Elocal_{waste\ water}$	**3.50E-03**	[$kg.d^{-1}$]	O

3.8.4.3.4 Meta SPC 4: Intended use 1.1 [Teat disinfection for lactating animals – manual dipping]

The emission estimation is based on Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.3 “Disinfection for veterinary hygiene: non-medical teat dips” (EN 2011). Therefore, two pathways into the environment are possible: emission to waste water and emission to slurry/ manure. The estimations are presented in the following tables.

Table 102: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Input parameters (ESD for PT3, 2011)

Parameter	Nomenclature	Value	Unit	Origin
Type of housing/manure storage (for application of the notification)	*cat-subcat (i1)*	i1= 1 (Dairy cows)	[-]	D
Type of biocide	*bioctype (i2)*	i2= 1 (Disinfectant)	[-]	D
Type of application	*appway (i3)*	i3= 2 (Dipping)	[-]	D
Relevant emission stream	*stream (i4)*	i4=1,2,3	[-]	P
Content of active ingredient in formulation (product)	*Fbioc*	3.25728	[$g.L^{-1}$]	S
Amount of (undiluted) product prescribed to be used for one treatment (dipping of the four teats) of one animal	$Vprod_{i3}$	0.010	[L]	S
Dilution factor (for preparation of the working solution from the formulation (product))	F_{dil} A)	1	[-]	S
Fraction of active ingredient released	F_{stp} $F_{slurry/manure}$ F) F_{air} F_{teat}	0.5 0.5 0.0 0.5	[-]	D

Number of teat dipping events for one animal and one day (dipping of the four teats of one animal = one disinfectant application)	*Napp-teat*	3	[-]	S
Number of days of lactation period (corresponds to number of emission days)	*Ndays-lact (= Temission)*	300	[d]	D
Number of disinfectant applications in one year (equals number of disinfectant applications on one lactation period)	*Napp-bioc*	900	[-]	O
Interval between two disinfectant applications (dipping events)	*Tbioc-int*[B)]	0.333	[d]	O
Number of manure applications for grassland (per year)	*Napp-grass*	4	[-]	D
Number of manure applications for agricultural land (per year)	*Napp-arab*	1	[-]	D
Manure application time interval for grassland	*Tgr-int*	53	[d]	D
Manure application time interval for arable land	*Tar-int*	212	[d]	S
Number of animals in housing	N_{animal}	100	[-]	D
Number of milk producing animal	$N_{mp\text{-}animal}$ [G)]	82	[-]	D
If nitrogen immission standards are applied: [C)]				
Nitrogen immission standard for one year on grassland	$Q_{N,grassland}$	170	[$kg.ha^{-1}$]	D
Nitrogen immission standard for one year on arable land	$Q_{N,arable\_land}$	170	[$kg.ha^{-1}$]	D
Mixing depth with soil, grassland	$DEPTH_{grassland}$ [D)]	0.05	[m]	D
Mixing depth with soil, arable land	$DEPTH_{arable\_land}$ [D)]	0.2	[m]	D
Density of wet bulk soil	$RHOsoil_{wet}$ [D,E)]	1700	[$kg.m^{-3}$]	D

A) For example: If the formulation is diluted 1/10 (= 1:10), the dilution factor is 10-1. If the formulation (product) is also used as working solution, the dilution factor is 1.

B) The interval between the end of a lactation period and the beginning of a new one was not taken into account in the default value for Tbioc-int in order not to underestimate the emission into the manure and consequently the soil exposure.

C) According to ESD for PT 18 No. 14.

D) According to ESD for PT 18 No. 14.

E) According to Technical Guidance Document on Risk Assessment (TGD) in support of Directive 98/8/EC, Part II (EC 2003a).

F) Degradation of the active substance in slurry/manure is not considered in the first tier. A methodology to include biodegradation in manure and slurry as second-tier approach in the emission estimation is provided in the ESD for PT 18 No. 14.

G) According to TAB ENV 63 (v. 2.0, 2018)

Table 103: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Intermediate calculations (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Number of biocide applications during storage period for application on grassland	$Napp\text{-}manure_{gr}$	159	[-]	O
Number of biocide applications during storage period for application on arable land	$Napp\text{-}manure_{ar}$	636	[-]	O
For grassland and arable land: If *Tbioc-int > Tgr/ar-int,* then *Napp-manure = 1* If *Tbioc-int < Tgr/ar-int,* then *Napp-manure = ROUND (Tgr/ar-int/Tbioc-int)* If *ROUND (Tgr/ar-int/Tbioc-int) > Napp-bioc,* then *Napp-manure = Napp-bioc* [A)] (ROUND is the sign for rounding off to a whole number)				
Amount of active ingredient to be used for one application	$Qai\text{-}prescr_{i1,i2,i3}$	3.257E-05	[kg]	O
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} \bullet Fbioc \bullet Vprod_{i1,i2,i3} \bullet F_{dil}$				
Amount of active ingredient in relevant stream *i4* after one application	*Qai*	1.335E-03	[kg]	O
Qai i1,i2,i3,i4 = Fstp or slurry/manure i1,i2,i3,i4 • Qai-prescr i1,i2,i3 • Nmp-animal1				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to grassland	$Qai\text{-}grass_{i1,i2,i3,i4}$	0.212	[kg]	O
$Qai\text{-}grass_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{gr}$				
Amount of active ingredient in manure or slurry after the relevant number of biocide applications for the manure application to arable land	$Qai\text{-}arab_{i1,i2,i3,i4}$	0.849	[kg]	O
$Qai\text{-}arab_{i1,i2,i3,i4} = Qai\text{-}slurry/manure_{i1,i2,i3,i4} \bullet Napp\text{-}manure_{ar}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to grassland	$Qnitrog\text{-}grass_{i1,i4}$	1796.17	[kg]	O
$Qnitrog\text{-}grass_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tgr\text{-}int_{i2}$				
Amount of nitrogen produced during the relevant period for every relevant (sub)category of animal/housing *i1* and application to arable land	$Qnitrog\text{-}arab_{i1,i4}$	7184.68	[kg]	O
$Qnitrog\text{-}arab_{i1,i4} = Nanimal_{i1} \bullet Qnitrog_{i1} \bullet Tar\text{-}int_{i2}$				

A) according to OECD ESD Number 14, chapter 5.9 (2006)

Table 104: Emission scenario for disinfectants used for veterinary hygiene: non-medical teat dips – Output parameters (ESD for PT3, 2011)

Parameters	Nomenclature	Value	Unit	Origin
Soil exposure				
For stream *i4* =1 and 3				
Concentration of the biocide (active ingredient) in soil (mg.kg^{-1}) in the case of an immission standard for nitrogen and land application on grassland (**four** manure applications per year are considered)	$PIECgrs\text{-}N_{i1,i2,i3,i4}$	**0.02364**	[mg.kg^{-1}]	O
Concentration of the biocide (active ingredient) in soil (mg.kg^{-1}) in the case of an immission standard for nitrogen and land application on arable land (**one** manure applications per year is considered)	$PIECars\text{-}N_{i1,i2,i3,i4}$	**0.00591**	[mg.kg^{-1}]	O
STP				
Local emission to a standard STP or an on-site waste water treatment plant	$Qai\text{-}stp_{i1,i2,i3,i4}$ = $Elocal_{waste\ water}$	**4.02E-03**	[kg.d^{-1}]	O

3.8.4.3.5 Meta SPC 5: Intended use 2.1 [Disinfection of animal houses – manual spraying]

The products within the meta SPC 5 of the BPF are intended to be used as disinfectant effective against bacteria, yeast and viruses in animal housings. The use is restricted for professionals only. The assessed scenario according to Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, chapter 2.1 “Disinfection of animal housings” (EN 2011) considers the disinfection of animal housing facilities in batch systems as a worst case. Before application all animals are moved out (e.g. at the end of a fattening period) and the stable is thoroughly cleaned. After the areas have dried, the disinfectant is applied by spraying the total surfaces with a low-pressure equipment (knapsack sprayer). The products within meta SPC 5 of the BPF contain the a.s. Iodine at a concentration of 2 % w/w which results in 20.0 g a.s./kg. By diluting the b.p. with water in a ratio 1:50, 1:100 respectively, a ready-to-use solution is prepared for the spraying application method which yield in a use concentration of 1-2 % w/w product and 0.02-0.04 % w/w available iodine, respectively. With a b.p. density of 1.0753 kg/m³, a conversion to w/v for the subsequent calculations has been performed.
For the treatment of 1 m² of the animal housing area, 200 - 400 mL of the ready-to-use solution are sufficient (≙ 4.3-8.6 g/m² of b.p. or 0.086-0.172 g/m² of a.s. respectively; conversion included). The following ERA reflects the use of 400 mL of the ready-to-use solution (2 % w/w or 2.15 % w/v respectively of the product), because this represents the worst case which covers also the use of the lower dosed RTU solution. The number of repeated treatments prescribed per animal (sub)category was provided by the applicant (specific b.p. data).
For the spraying application, releases via air are supposed to be zero in accordance to ESD for PT3 (EN 2011). Thus, releases of a.s. residues to the environment occur only via manure/slurry and STP. The release estimations are presented in the following tables.

Table 105: Emission scenario for disinfectants used for disinfection of animal housings – Input and Output parameters (ESD for PT3, 2011)

Determinants of the emission scenario according to chapter 2.1 in OECD ESD PT 3 (2011)		Value
Type of housing (for application *m* of the notification) *cat-subcat (i1)*		4 - 18
Type of disinfectant *bioctype (i2)*		1 (all disinfectants)
Type of application n *appway (i3)*		1 (spraying)
Type of manure storage *manstore (i4)*		1 – 3 (all waste streams)
Input		
Maximum immission standards	- for nitrogen on grassland	170 $kg.ha^{-1}.yr^{-1}$
	- for nitrogen on arable land	170 $kg.ha^{-1}.yr^{-1}$
Number of repeated treatments prescribed		1 for i1= 5, 7-11, 13-15
		2 for i1= 6, 16, 18
		8 for i1= 4, 12
		10 for i1= 17
Period between biocide treatments		365 for i1= 5, 7-11, 13-15
		183 for i1= 6, 16, 18
		46 for i1= 4, 12
		37 for i1= 17
Number of land application	- on grassland	4 yr^{-1}
	- on arable land	1 yr^{-1}
Manure storage time	- grassland	53 d
	- arable land	212 d
Content of active ingredient in formulation		2%
Quantity of commercial product to be used		8.6 g/m²
Content of active ingredient in ready-to-use solution		2%
Output		
Number of biocide application during manure storage period for application	- on grassland (ref. to intermediate calculations ESD No. 14, p. 55)	One within the four intervals for i1= 5, 7-11, 13-15
		Two within the four intervals for i1= 6, 16, 18
		Five within the four intervals for i1= 4, 12
		Six within the four intervalsfor i1= 17
	- on arable land	1 for i1= 5, 7-11, 13-15
		2 for i1= 6, 16, 18
		5 for i1= 4, 12
		6 for i1= 17

In dependence of the different relevant streams (see chapter 3.8.4.5), the type of animal housing ‘sows in individual pens’ represents the worst case in case that only slurry is applied on agricultural areas. In case that there is no connection to the local sewer system and slurry/manure and waste water are mixed together and applied to agricultural land, the type of animal housing ‘ducks’ represents the worst case. If the waste water stream is considered (connection to the local sewer system), the type of animal housing ‘turkeys’ represents the worst case. An overview of default and specific values for disinfection application for this worst-case animal housings is presented in the following table:

Table 106: Overview of default and specific values for disinfection application in housings of sows in individual pens, turkeys and ducks

Determinants of the emission scenario according to chapter 2.1 in ESD PT 3 (2011)		**Value**						
Input		**Sows in individual pens**	**Turkeys**			**Ducks**		
Category-subcategory *i1*		4	16			17		
Considered area of the housing for application *m* [m²]		1930	8040			4880		
Number of animals in the housing		132	10000			10000		
Fraction of active ingredient released to relevant compartment		0.5 slurry	0.3 slurry	0.2 waste water (ww)	0.5 slurry + ww	0.3 manure	0.2 waste water (ww)	0.5 manure + ww
Average amounts of	– liquid waste per animal	-	-	0.08 kg.d^{-1}		-	0.08 kg.d^{-1}	
	– nitrogen per animal	0.07106 kg/d	0.00482 kg/d			0.00274 kg/d		
Output								
Amount of product prescribed to be used for area specified for application *m* [kg]		16.60	69.14			41.97		
Amount of active ingredient to be used for one b.p. application [kg]		0.332	1.38			0.839		
Amount of a.s. in relevant stream *i4* after one b.p. application [kg]		0.166	0.415	0.277	0.691	0.252	0.168	0.420
Amount of nitrogen produced during the relevant period [kg]	– for application on arable land	1.99 x 10^{3}	1.02 x 10^{4}	-	1.02 x 10^{4}	5.81 x 10^{3}	-	5.81 x 10^{3}
	– for application on grassland	4.97 x 10^{2}	2.56 x 10^{3}	-	2.56 x 10^{3}	1.45 x 10^{3}	-	1.45 x 10^{3}
Amount of waste water produced during the relevant period [kg]		-	-	1.46 x 10^{5}	-	-	2.96 x 10^{4}	-
PIEC/PEC of a.s. in soil based on nitrogen immission standard [mg.kg^{-1}]	– for arable land	1.39 x 10^{-1}	2.71 x 10^{-2}	-	4.52 x 10^{-2}	8.68 x 10^{-2}	-	1.45 x 10^{-1}
	– for grassland	2.31 x 10^{-1}	4.50 x 10^{-2}	-	7.50 x 10^{-2}	1.44 x 10^{-1}	-	2.40 x 10^{-1}

Determinants of the emission scenario according to chapter 2.1 in ESD PT 3 (2011)	Value						
Concentration of a.s. in waste water in relevant period [$mg.kg^{-1}$]	-	-	1.89	-	-	5.67	-
Local emission rate of a.s. to waste water [$kg.d^{-1}$]	-	-	0.277	-	-	0.168	-

3.8.4.4 *Foreseeable routes of entry into the environment on the basis of the use envisaged for meta SPC 1 to 4*

The use of the products within the meta SPC 1 to 4 of the BPF to treat against bacteria and yeast in veterinary udder hygiene result in exposure of the environment indirect via STP to water, sediment, soil and groundwater as well as direct to terrestrial compartments.

Table 107: Identification of relevant receiving compartments based on the exposure pathway

Meta SPC	Use No.	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air
1, 2, 3 and 4	Use 1.1	yes	yes (indirect)	yes (direct + indirect)	not relevant
1 and 2	Use 1.2	yes	yes (indirect)	yes (direct + indirect)	not relevant
1 and 2	Use 1.3	yes	yes (indirect)	yes (direct + indirect)	not relevant
1 and 2	Use 1.4	yes	yes (indirect)	yes (direct + indirect)	not relevant
1 and 2	Use 1.5	yes	yes (indirect)	yes (direct + indirect)	not relevant

3.8.4.5 *Foreseeable routes of entry into the environment on the basis of the use envisaged for meta SPC 5*

The products within the meta SPC 5 of the BPF are notified for disinfection application in poultry and pig breeding areas, the calculation were conducted for all of relevant categories and subcategories (pigs: 4-6; poultry: 7-18). In dependence of the relevant emission streams different exposure pathway scenarios exist:

In case of livestock, the relevant emission stream is only slurry. Contrary, the relevant emission stream of housing systems for poultry is depicted by:

- discharge of stable cleaning water to the municipal STP and slurry (battery cages with aeration)
- manure and liquid waste (free-range system with litter floor)
- solely slurry (free-range with grating floor, battery cages without treatment and compact battery cages) and
- solely manure (battery cages with forced drying).

In case that the poultry housing system is not connected to the local sewer system, the waste water from the housing would remain on site and be stored in a specific collection tank. Then, waste water will be mixed with slurry/manure and will commonly be applied to agricultural land.
In case that the animal housing is connected to the local sewer system, a fraction of a.s. could be released with waste water to the local STP whilst another fraction of a.s. could be applied to agricultural land after a period of storage in manure/slurry (ref. to ESD PT 3, p. 19f., EN 2011).
Thus, two different scenarios must be assessed for the receiving as well as secondarily affected environmental compartments for the life cycle stage ‘professional use phase’ according to the ESD PT3 (2011). In Table 108 both scenarios, poultry housing is connected to the local sewer system (“via STP”)

and pig and poultry housing which are not connected to the local sewer system ("via manure/slurry"), with the relevant receiving compartments are summarised.

Table 108: Identification of relevant receiving compartments based on the exposure pathway

	Wastewater (STP)	Surface water and Sediment	Soil and Groundwater	Air
via STP	yes	yes (indirect)	yes (indirect)	not relevant
via manure/slurry	no	yes (indirect)	yes (direct)	not relevant

3.8.4.6 *Fate and distribution in exposed environmental compartments*

Whereas the term degradation is not applicable to an element, iodine may undergo different hydrolytic, photolytic and microbial transformation processes (i.e. speciation) in the different compartments. The presence of different forms of iodine is largely dependent on redox potential and pH. Iodide (I^-) and iodate (IO_3^-) are the dominant iodine species in soil. Iodate is the dominant chemical form of iodine in the soil solution under non-flooded conditions whilst under flooded conditions iodide is the dominant chemical form. In water, the prevalent iodine forms are iodide and iodate. In surface waters, the proportion of iodide to iodate will vary depending on microbial activity and the release of iodine species from terrestrial sources.
Iodine as an element does not undergo biodegradation processes but biotic transformation processes may be involved in the formation of the different iodine species.
Hydrolysis of iodine takes place in a series of reactions and leads to the formation of iodide and iodate. Natural waters, particularly marine waters, contain iodine mainly in the form of iodide and iodate. Iodide (oxidation state -1) is the dominant iodine species in surface waters due to its stability in the most environmental conditions whilst iodate (oxidation state of iodine +5)) is found predominantly under alkaline and well oxidized conditions. .
Adsorption data for iodine has been acquired from an adsorption screening test according to OECD 106 and from publicly available information. A geometrical mean K_{OC} of 165.8 cm^3/g was calculated from the OECD 106 test in the CAR. However, the adsorption of iodine to soil is not only attributed to organic matter, even though this type of adsorption seems to be predominant at pH > 6. A different approach is therefore applied, i.e. to use measured partitioning coefficients K_d (or Kp_{comp} as given in the Guidance on the BPR, Vol. IV, Part B (2015)) for soil and suspended matter directly. In conclusion, and in agreement with the statement in section 2.3.5.3 in the Guidance on the BPR, Vol. IV, Part B (2015) that for ionic substances measured adsorption coefficients are needed, the solids-water adsorption coefficients to be used the environmental exposure calculations are Kp_{soil} = 5.8 cm^3/g and Kp_{susp} = 2.2 x 10^2 cm^3/g.

Table 109: Input parameters (only set values) for calculating the fate and distribution in the environment, according to CAR (2013) on iodine

Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	according to LoEP (AR 2013, eCA SE)
Melting point	113.7	°C	according to LoEP (AR 2013, eCA SE)
Boiling point	184.5	°C	according to LoEP (AR 2013, eCA SE)
Vapour pressure (at 25°C)	1 x 10^{-6}	Pa	according to CAR Doc

			IIA, used for EEA (eCA SE,2013)
Water solubility (at 25°C)	100	g/L	according to CAR Doc IIA, used for EEA (eCA SE,2013)
Log Octanol/water partition coefficient	2.49	Log 10	according to CAR Doc IIA (eCA SE,2013)
Organic carbon/water partition coefficient (Koc)	165.83	L/kg	geomean according to CAR Doc IIA, used for EEA (eCA SE,2013)
Solids-water partitioning coefficient in soil	5.8	L/kg	geomean according to CAR Doc IIA, used for EEA (eCA SE,2013)
Solids-water partitioning coefficient in sediment	200	L/kg	geomean according to CAR Doc IIA, used for EEA (eCA SE,2013)
Solids-water partitioning coefficient in suspended matter	220	L/kg	geomean according to CAR Doc IIA, used for EEA (eCA SE,2013)
Henry's Law Constant (at 12°C)	1.22×10^{-9}	$Pa/m^3/mol$	calculated value
Biodegradability			a.s. is not biodegradable
DT_{50} for degradation in soil	1E+06	d	Default

Normally, RefMS would appreciate to use the arithmetic mean endpoints. However, since geometric mean was used to generate the endpoints in frame of the environmental exposure assessment in CAR (2013) on iodine, for a consistent assessment the RefMS decided to abide by that decision.

The distribution and degradation of the a.s. in the STP are based on literature data according to CAR (2013) on iodine. Therefore, following values are used for the environmental exposure assessment: The fraction of emissions directed to water (F_{water}) are set to 80 %, the fraction of emissions directed to sludge (F_{sludge}) are set to 20 % and to air (F_{air}) are set to 0 %, the fraction degraded in STP are set to 0 %.

Because iodine is an inorganic compound, no biodegradation in manure or waste water / sewage sludge is considered. Only transformation processes from iodine in iodide and iodate in relation to the different environmental conditions are considered (ref. to figures in Doc.II-B of CAR (2013) on iodine). Therefore it should be noted, that the molecular weight of 2 iodide ions corresponds to the molecular weight of iodine, consequently the PECs for iodide are the same as for iodine. The molecular weight of 2 iodate ions is a factor of 1.3782 higher than the molecule weight of iodine, therefore the PECs for iodate were calculated by multiplying the PECs of iodine by this factor (Checking the value leads to a different result as compared to CAR (2013) on iodine (1.382); corrected value was used for the environmental risk assessment).
Furthermore, the formation fraction for iodine and iodate depending on the environmental conditions in the relevant compartment has to be considered (ref. to Figure 1 and Figure 2, cited from CAR (2013) on iodine).

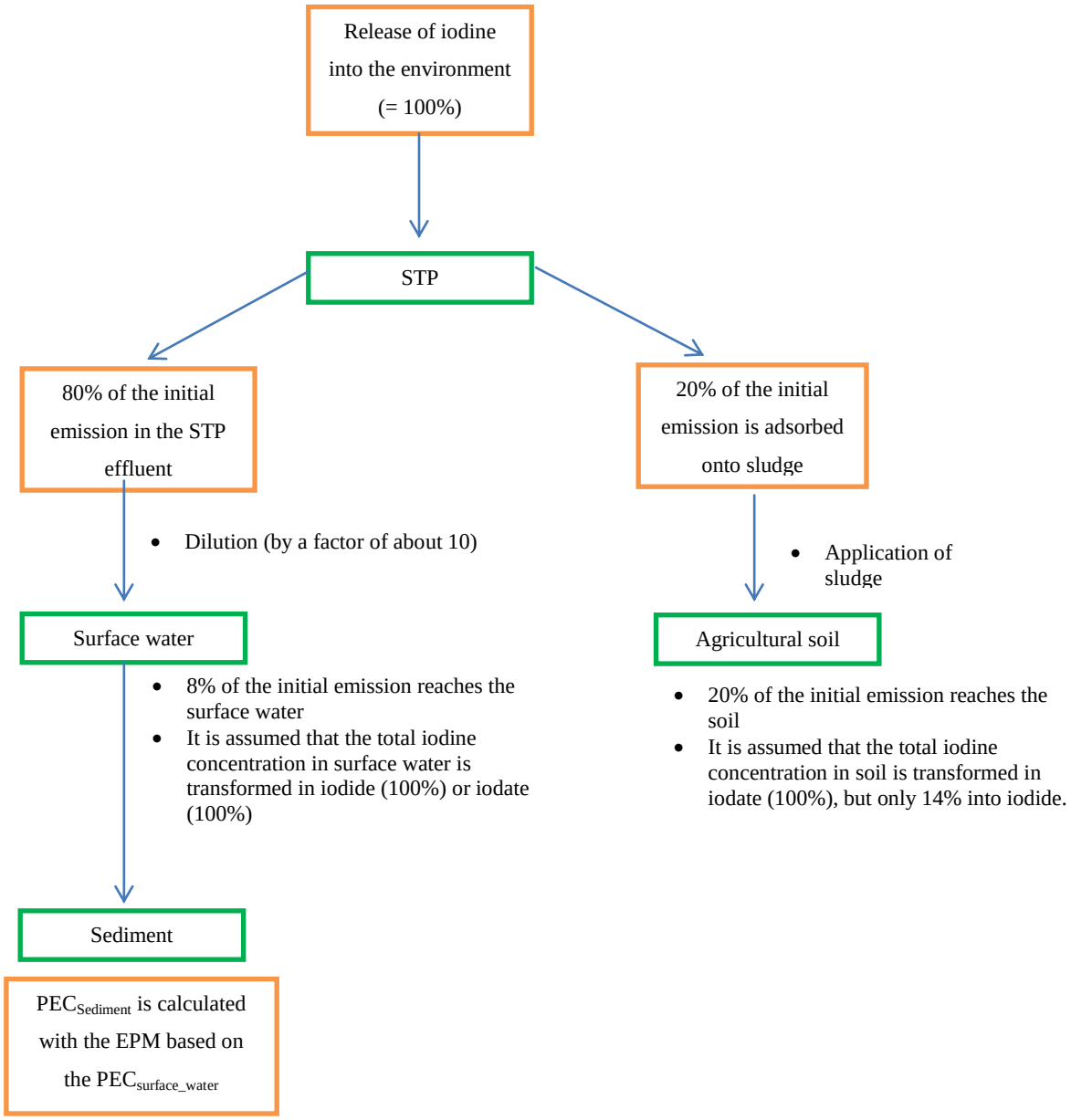

Figure 1: Distribution flowchart of iodine and its formation products for the emission pathway via STP (CAR 2013)

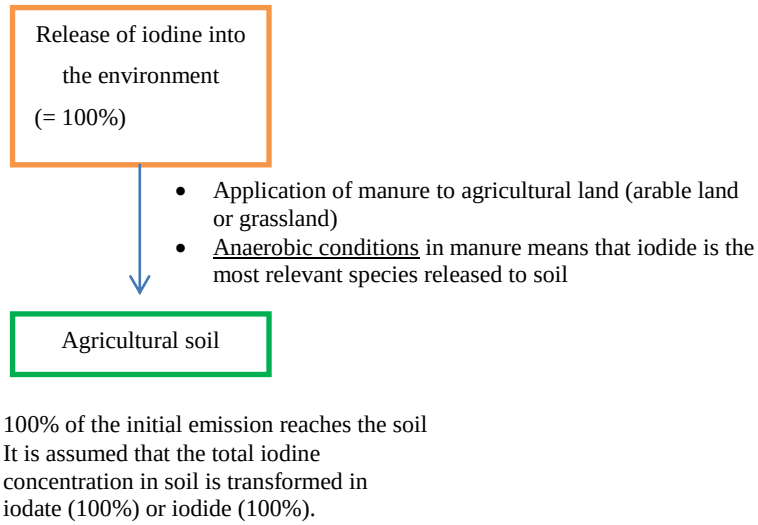

Figure 2: Distribution flowchart of iodine and its formation products for the emission pathway via manure/slurry (CAR 2013)

3.8.4.7 *Calculated PEC values for meta SPC 1 to 4*

3.8.4.7.1 Local PEC values for the emission pathway via manure/slurry

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 27 and 29 of OECD ESD No. 14 on which ESD PT 3 refers and adapted to TAB ENV entry ENV 11 (v. 2.0, 2018);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{soil} according to equation 24 b and 25 b of the Recommendation of the AHEE, Addendum to OECD ESD No. 14 on which ESD PT 3 refers (BPC WG ENV V, 2015) considering recent decisions concerning the parameters $Tgr\text{-}int_{no\_manure}$ (365 d instead 206 d) and k_{leach} (according to eq. 58, Guidance on the BPR, Vol. IV, Part B (2015)).;
- $PEC_{groundwater}$ according to equation 26 and 28 of OECD ESD No. 14 on which ESD PT 3 refers and adapted to equation 37 of the Recommendation of the AHEE, Addendum to OECD ESD No. 14.

Phosphorous immission standards were not considered in the current assessment since they are unique in the Netherlands and therefore not applicable EU wide. At the technical meeting I/08 it was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1}.yr^{-1}$ for all soils (arable land and grassland).

The distribution for the emission pathway via manure/slurry application is corresponding to Figure 2.

Iodine is assumed to transform into non-volatile iodide and iodate in the different environmental compartments. Consequently, air is not an environmental compartment of concern (CAR (2013) on iodine) and subsequently PEC_{air} calculations are not relevant.

The local PEC values for meta SPC 1 to 4 from the intended use 1.3 (meta SPC 1 and 2) or the intended use 1.1 (meta SPC 3 and 4) are presented in the following tables and are used for the environmental risk assessment:

Table 110: Meta SPC 1 - Summary table on calculated PEClocal values for meta SPC 1 from the intended uses 1.3 (dairy cows, manual teat spraying; pathway via slurry/manure; based on nitrogen immission standard)

Use	Chemical speciation	$PEC_{surface\_water}$		PEC_{sed}		PEC_{soil}		PEC_{GW}		PEC_{air}
		arable land	grass-land	arable land	grass-land	arable land	grass-land	arable land	grass-land	
		[µg/L]		[µg/kg_{wwt}]		[µg/kg_{wwt}]		[µg/L]		[mg/m^3]
1.3	Iodine	0.96	5.27	46.47	255.93	50.24	276.53	9.60	52.82	---
	Iodate	1.32	7.26	64.07	352.71	60.23	381.12	13.23	72.80	---
	Iodide	0.96	5.27	46.47	255.93	50.24	276.53	9.60	52.82	---

Table 111: Meta SPC 2 - Summary table on calculated PEClocal values for meta SPC 2 from the intended uses 1.3 (dairy cows, manual teat spraying; pathway via slurry/manure; based on nitrogen immission standard)

Use	Chemical speciation	$PEC_{surface\_water}$		PEC_{sed}		PEC_{soil}		PEC_{GW}		PEC_{air}
		arable land	grass-land	arable land	grass-land	arable land	grass-land	arable land	grass-land	
		[µg/L]		[µg/kg_{wwt}]		[µg/kg_{wwt}]		[µg/L]		[mg/m^3]
1.3	Iodine	1.10	6.07	53.57	294.91	57.89	318.66	11.06	60.87	---
	Iodate	1.52	8.36	73.84	406.42	79.78	439.18	15.24	83.89	---
	Iodide	1.10	6.07	53.57	294.91	57.89	318.66	11.06	60.87	---

Table 112: Meta SPC 3 - Summary table on calculated PEClocal values for meta SPC 3 from the intended uses 1.1 (dairy cows, manual teat dipping; pathway via slurry/manure; based on nitrogen immission standard)

Use	Chemical speciation	$PEC_{surface\_water}$		PEC_{sed}		PEC_{soil}		PEC_{GW}		PEC_{air}
		arable land	grass-land	arable land	grass-land	arable land	grass-land	arable land	grass-land	
		[µg/L]		[µg/kg_{wwt}]		[µg/kg_{wwt}]		[µg/L]		[mg/m^3]
1.1	Iodine	0.65	3.60	31.79	174.94	34.34	189.04	6.56	36.11	---
	Iodate	0.90	4.96	43.80	241.10	47.33	260.53	9.04	49.76	---
	Iodide	0.65	3.60	31.79	174.94	34.34	189.04	6.56	36.11	---

Table 113: Meta SPC 4 - Summary table on calculated PEClocal values for meta SPC 4 from the intended uses 1.1 (dairy cows, manual teat dipping; pathway via slurry/manure; based on nitrogen immission standard)

Use	Chemical speciation	$PEC_{surface\_water}$		PEC_{sed}		PEC_{soil}		PEC_{GW}		PEC_{air}
		arable land	grass-land	arable land	grass-land	arable land	grass-land	arable land	grass-land	
		[µg/L]		[µg/kg_{wwt}]		[µg/kg_{wwt}]		[µg/L]		[mg/m^3]
1.1	Iodine	0.75	4.14	36.51	201.00	39.46	217.19	7.54	41.49	---
	Iodate	1.04	5.70	50.31	277.02	54.38	299.34	10.39	57.18	---
	Iodide	0.75	4.14	36.51	201.00	39.46	217.19	7.54	41.49	---

3.8.4.7.2 Local PEC values for the emission pathway via STP

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{eff}$) according to equation 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

According to the proposed use of b.p. the interval between two releases is shorter than one month and therefore, the effluent concentration is representative for the exposure of microorganisms in STP. Thus,

- PEC_{STP} = $Clocal_{eff}$ referring to equation 38, chapter 2.3.7.1, Guidance BPR IV ENV B (2015).

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 66, chapter 2.3.8.5, Guidance BPR IV ENV B (2015);
- $PEC_{local\_groundwater}$ according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015) as a first worst-case estimation.

The distribution for the emission pathway via STP application is corresponding to Figure 1.

Iodine is assumed to speciate into non-volatile iodide and iodate in the different compartments it is released to. Consequently, air is not an environmental compartment of concern (CAR (2013) on iodine) and subsequently PEC_{air} calculations are not relevant.

The local PEC values for meta SPC 1 to 4 from the intended use 1.3 (meta SPC 1 and 2) or the intended use 1.1 (meta SPC 3 and 4) are presented in the following tables and are used for the environmental risk assessment:

Table 114: Meta SPC 1 - Summary table on calculated PEClocal values for meta SPC 1 from the intended uses 1.3 (dairy cows, manual teat spraying; pathway via STP)

Use	Chemical speciation	PEC_{STP} [µg/L]	$PEC_{surface\_water}$ [µg/L]	PEC_{sed} [$\mu g/kg_{wwt}$]	PEC_{soil} [$\mu g/kg_{wwt}$]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
1.3	Iodine	2.045	0.204	9.916	12.655	2.369	---
	Iodate	2.819	0.281	13.666	17.441	3.265	---
	Iodide	2.045	0.204	9.916	1.772	0.332	---

Table 115: Meta SPC 2 - Summary table on calculated PEClocal values for meta-SPC 2 from the intended uses 1.3 (dairy cows, manual teat spraying; pathway via STP)

Use	Chemical speciation	PEC_{STP} [µg/L]	$PEC_{surface\_water}$ [µg/L]	PEC_{sed} [$\mu g/kg_{wwt}$]	PEC_{soil} [$\mu g/kg_{wwt}$]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
1.3	Iodine	2.357	0.235	11.423	14.583	2.730	---
	Iodate	3.248	0.324	15.743	20.098	3.762	---
	Iodide	2.357	0.235	11.423	2.042	0.382	---

Table 116: Meta SPC 3 - Summary table on calculated PEClocal values for meta-SPC 3 from the intended uses 1.1 (dairy cows, manual teat dipping; pathway via STP)

Use	Chemical speciation	PEC_{STP} [µg/L]	$PEC_{surface\_water}$ [µg/L]	PEC_{sed} [$\mu g/kg_{wwt}$]	PEC_{soil} [$\mu g/kg_{wwt}$]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
1.1	Iodine	1.398	0.139	6.771	8.650	1.619	---
	Iodate	1.927	0.192	9.332	11.922	2.232	---
	Iodide	1.398	0.139	6.771	1.211	0.227	---

Table 117: Meta SPC 4 - Summary table on calculated PEClocal values for meta-SPC 4 from the intended uses 1.1 (dairy cows, manual teat dipping; pathway via STP)

Use	Chemical speciation	PEC_{STP} [µg/L]	$PEC_{surface\_water}$ [µg/L]	PEC_{sed} [$\mu g/kg_{wwt}$]	PEC_{soil} [$\mu g/kg_{wwt}$]	PEC_{GW} [µg/L]	PEC_{air} [mg/m^3]
1.1	Iodine	1.606	0.160	7.782	9.940	1.861	---
	Iodate	2.214	0.221	10.725	13.699	2.564	---
	Iodide	1.606	0.160	7.782	1.392	0.261	---

3.8.4.8 *Calculated PEC values for meta SPC 5*

3.8.4.8.1 **Local PEC values for the emission pathway via manure/slurry**

The estimation of the local PECs for the aquatic compartment includes PECs for surface water and sediment:

- $PEC_{surfacewater}$ according to equation 27 and 29 of OECD ESD No. 14 on which ESD PT 3 refers and adapted to TAB ENV entry ENV 11 (v. 2.0, 2018);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{soil} according to equation 24 b and 25 b of the Recommendation of the AHEE, Addendum to OECD ESD No. 14 on which ESD PT 3 refers (BPC WG ENV V, 2015) considering recent decisions concerning the parameters $Tgr\text{-}int_{no\_manure}$ (365 d instead 206 d) and k_{leach} (according to eq. 58, Guidance on the BPR, Vol. IV, Part B (2015)).;
- $PEC_{groundwater}$ according to equation 26 and 28 of OECD ESD No. 14 on which ESD PT 3 refers and adapted to equation 37 of the Recommendation of the AHEE, Addendum to OECD ESD No. 14.

Phosphorous immission standards were not considered in the current assessment since they are unique in the Netherlands and therefore not applicable EU wide. At the technical meeting I/08 it was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1}.yr^{-1}$ for all soils (arable land and grassland).

The distribution for the emission pathway via manure/slurry application is corresponding to Figure 2.

Iodine is assumed to transform into non-volatile iodide and iodate in the different environmental compartments. Consequently, air is not an environmental compartment of concern (CAR (2013) on iodine) and subsequently PEC_{air} calculations are not relevant.

The local PEC values for meta SPC 5 via manure/slurry are presented in the following tables and are used for the environmental risk assessment:

Table 118: Predicted environmental concentrations (PECs) for meta SPC 5 via manure/slurry in surface water (slurry/manure ≙ i1=4; slurry/manure + waste water ≙ i1=17)

System	Chemical speciation	$PEC_{surface\ water}$ slurry/manure		$PEC_{surface\ water}$ slurry/manure + waste water	
		arable land	grassland	arable land	grassland
		[µg.L^{-1}]		[µg.L^{-1}]	
Nitrogen limited immission	Iodine	2.42	4.01	2.51	4.17
	Iodate	3.33	5.53	3.46	5.74
	Iodide	2.42	4.01	2.51	4.17

Table 119: Predicted environmental concentrations (PECs) for meta SPC 5 via manure/slurry in sediment (slurry/manure ≙ i1=4; slurry/manure + waste water ≙ i1=17)

System	Chemical speciation	$PEC_{sediment}$ slurry/manure		$PEC_{sediment}$ slurry/manure + waste water	
		arable land	grassland	arable land	Grassland
		[µg.kg^{-1}]		[µg.kg^{-1}]	
Nitrogen limited immission	Iodine	1.18 x 10^2	1.95 x 10^2	1.22 x 10^2	2.03 x 10^2
	Iodate	1.62 x 10^2	2.69 x 10^2	1.68 x 10^2	2.79 x 10^2
	Iodide	1.18 x 10^2	1.95 x 10^2	1.22 x 10^2	2.03 x 10^2

The grassland scenario represents the worst-case values for the estimated PECs in the aquatic compartments for both 'sows in individual pens' (i1=4, considering only slurry/manure) and 'ducks' (i1=17; considering slurry/manure plus waste water).

Table 120: Predicted environmental concentrations (PECs) for meta SPC 5 via manure/slurry for the terrestrial environment compartments

Cat - subcat	Index i1	Waste stream	Chemical speciation	PEC_{soil}		$PEC_{groundwater}$	
				arable land	grassland	arable land	grassland
				[mg.kg^{-1}]		[µg.L^{-1}]	
Sows in individual pens	4	slurry	Iodine	1.39 x 10^{-1}	2.31x 10^{-1}	26.61	44.15
			Iodate	1.92 x 10^{-1}	3.19 x 10^{-1}	36.67	60.85
			Iodide	1.39 x 10^{-1}	2.31x 10^{-1}	26.61	44.15
Ducks	17	Waste water + manure	Iodine	1.45 x 10^{-1}	2.40 x 10^{-1}	27.64	45.86
			Iodate	1.99 x 10^{-1}	3.31 x 10^{-1}	38.09	63.21
			Iodide	1.45 x 10^{-1}	2.40 x 10^{-1}	27.64	45.86

Again, the grassland scenario represents the worst-case values for the estimated PECs as well in the terrestrial compartments for both 'sows in individual pens' (i1=4, considering only slurry/manure) and 'ducks' (i1=17; considering slurry/manure plus waste water).

3.8.4.8.2 Local PEC values for the emission pathway via STP

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= $Clocal_{inf}$) according to equation 39, chapter 2.3.7.1, Guidance BPR IV ENV B (2015);
- $PEC_{local\_surfacewater}$ according to equation 48, chapter 2.3.8.3, Guidance BPR IV ENV B (2015);
- $PEC_{local\_sediment}$ according to equation 50, chapter 2.3.8.4, Guidance BPR IV ENV B (2015).

According to the proposed use of b.p. there is an intermittent release to STP (interval between two releases is longer than one month) and therefore, the influent concentration is representative for the exposure of microorganisms in STP. Thus,

- PEC_{STP} = $Clocal_{inf}$ referring to equation 39, chapter 2.3.7.1, Guidance BPR IV ENV B (2015).

The estimation of the local PECs for the terrestrial compartment includes PECs for soil and groundwater:

- PEC_{local_soil} according to equation 66, chapter 2.3.8.5, Guidance BPR IV ENV B (2015);
- $PEC_{local\_groundwater}$ according to equation 68, chapter 2.3.8.6, Guidance BPR IV ENV B (2015) as a first worst-case estimation.

The distribution for the emission pathway via STP application is corresponding to Figure 1.

Iodine is assumed to transform into non-volatile iodide and iodate in the different compartments. Consequently, air is not an environmental compartment of concern (CAR (2013) on iodine) and subsequently PEC_{air} calculations are not relevant.

As it was pointed out in chapter 3.8.4.5 as well as it is shown in Table 106, in some animal housing systems, particularly for poultry (category-subcategory 8, 11, 12, 16-18) a fraction of applied biocidal product can be released to waste water that is discharged to a STP. Release fractions to waste water for these animal categories were calculated according to OECD ESD No. 14 on which ESD PT 3 refers. The input and output data for calculation of local emission rate of a.s. to waste water is given in Table 106 as an example for application in turkey housings (worst-case). Further calculation of influent and effluent concentration in STP, PEC_{STP}, $PEC_{surface\_water}$ were carried out by assuming that only one farm releases liquid wastes into the sewer at one day.

The local PEC values for meta SPC 5 from the intended via STP are presented in the following tables and are used for the environmental risk assessment:

Table 121: Summary table on predicted environmental concentrations (PECs) for meta SPC 5 via STP for the aquatic environment compartments

Cat - subcat	Index i1	Chemical speciation	$Clocal_{inf}$ [mg/L]	$Clocal_{eff}$ [mg/L]	PEC_{STP} [mg/L]	$PEClocal_{surface\_water}$ [mg/L]	$PEClocal_{sediment}$ [mg/kg]
Turkeys	16	Iodine	0.138	0.111	0.138	0.011	0.536
		Iodate	0.191	0.153	0.191	0.0152	0.739
		Iodide	0.138	0.111	0.138	0.011	0.536

Table 122: Summary table on predicted environmental concentrations (PECs) for meta SPC 5 via STP for the terrestrial environment compartments

Cat - subcat	Index i1	Chemical speciation	C_{sludge} [mg/kg]	$PEClocal_{soil}$ [mg/kg]	$PEClocal_{groundwater}$ [mg/L]
Turkeys	16	Iodine	70	0.685	0.128
		Iodate	965	0.944	0.177
		Iodide	70	0.0958	0.0179

3.8.4.9 *Non-compartment specific effects*

A log K_{OW} of 2.49 was determined for iodine, which is below the relevant trigger value of 3 as stated in the Guidance BPR IV ENV B (2015). It can be assumed that the potential for iodine to bio-accumulate is low. Furthermore, as the amounts of iodine put into the environment through biocidal uses are within the natural occurring background levels, there is no concern with respect to secondary poisoning (CAR (2013) on iodine).

3.8.4.10 *Aggregated exposure (combined for relevant emission sources)*

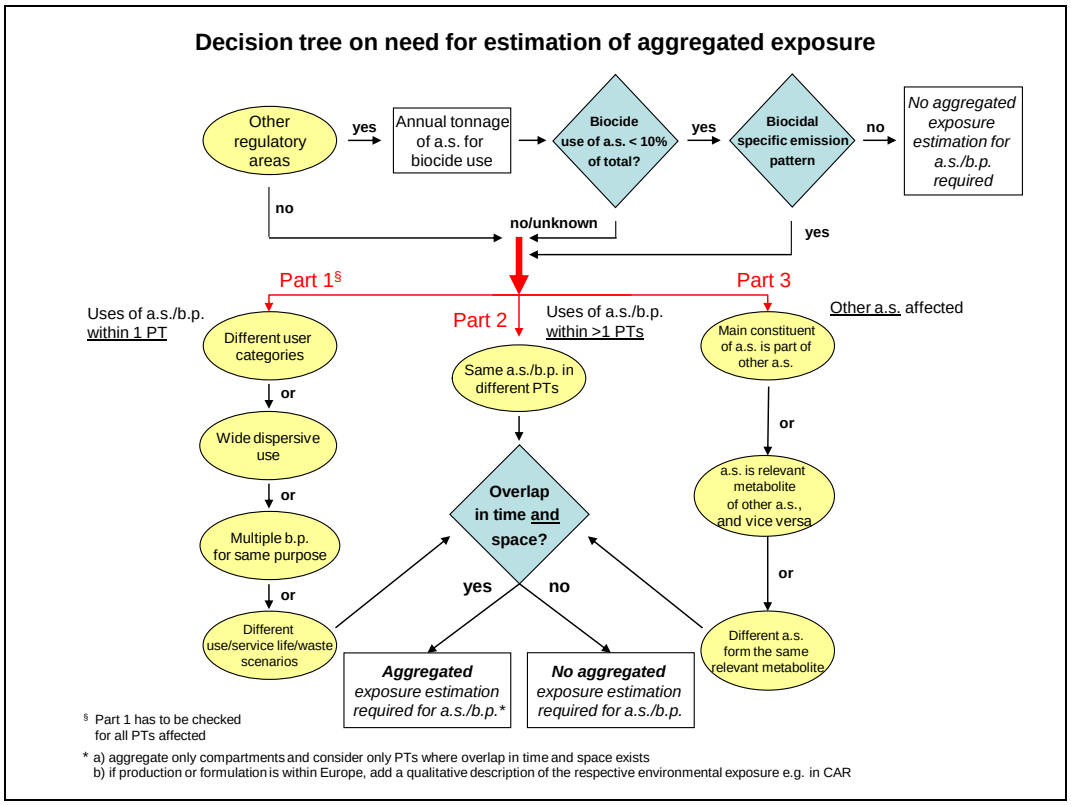

Figure 3: Decision tree on the need for estimation of aggregated exposure

According to the "Decision tree on need for estimation of aggregated exposure" the requirement for aggregated exposure estimations was checked for products of the BPF. The BPF contains as a.s. iodine. This a.s. is also evaluated in the frame of other regulatory areas (e.g. pharmaceuticals).
The iodine world demand in the year 2006 for the production of disinfectants was 14 % of the total iodine world demand of 25,000 – 26,000 t/year. Thus, about 3640 t iodine/year were used for the production of disinfectants throughout the world (CAR on iodine, 2013). Therefore the bottom half of the decision tree has to be checked.

- to Part 1:

Because iodine will be used as disinfectant in animal housings and for teat disinfection, there is the possibility that an overlapping application in time and space of iodine containing products can occur.

Regarding the use of the products of the BPF, the same environmental exposure pathway has been identified:

- Release of iodine due to spraying application in poultry housings or dipping for teat disinfection with subsequent release via STP to aquatic compartment (surface water and sediment) and via sludge deposition to terrestrial compartment (soil and groundwater).
- Release of iodine due to spraying application in animal housings or dipping for teat disinfection with subsequent release via manure/slurry application direct to agricultural soils and groundwater and indirect to surface water (via runoff) and sediment.

In the CAR on iodine (2013) the decision tree on the need for estimation of aggregated exposure was not adopted. Therefore, the eCA (Sweden) discuss the possibility of aggregated exposure in general instead each of the three parts of the tree separately. Some of these considerations were assumed as well by the RefMS for the BPF.
So it is not considered as relevant that manure from different domestic animals is spread onto the same agricultural field. Furthermore, it is not assumed that both manure and sewage sludge are applied to the same agricultural field. In consequence, no aggregated exposure assessment has to be performed for soil and the same applies for groundwater as subsequent compartment. The situation is quite different for surface water since both release from STP and runoff from agricultural land have to be considered in the aggregated exposure assessment and for sediment as subsequent compartment. Consequently, the RefMS opinion is that an aggregated exposure estimation for a.s./b.p. is required.

The flowchart below depicts the choice of the relevant emission pathways and names the resulting environmental compartments for an aggregated exposure assessment.

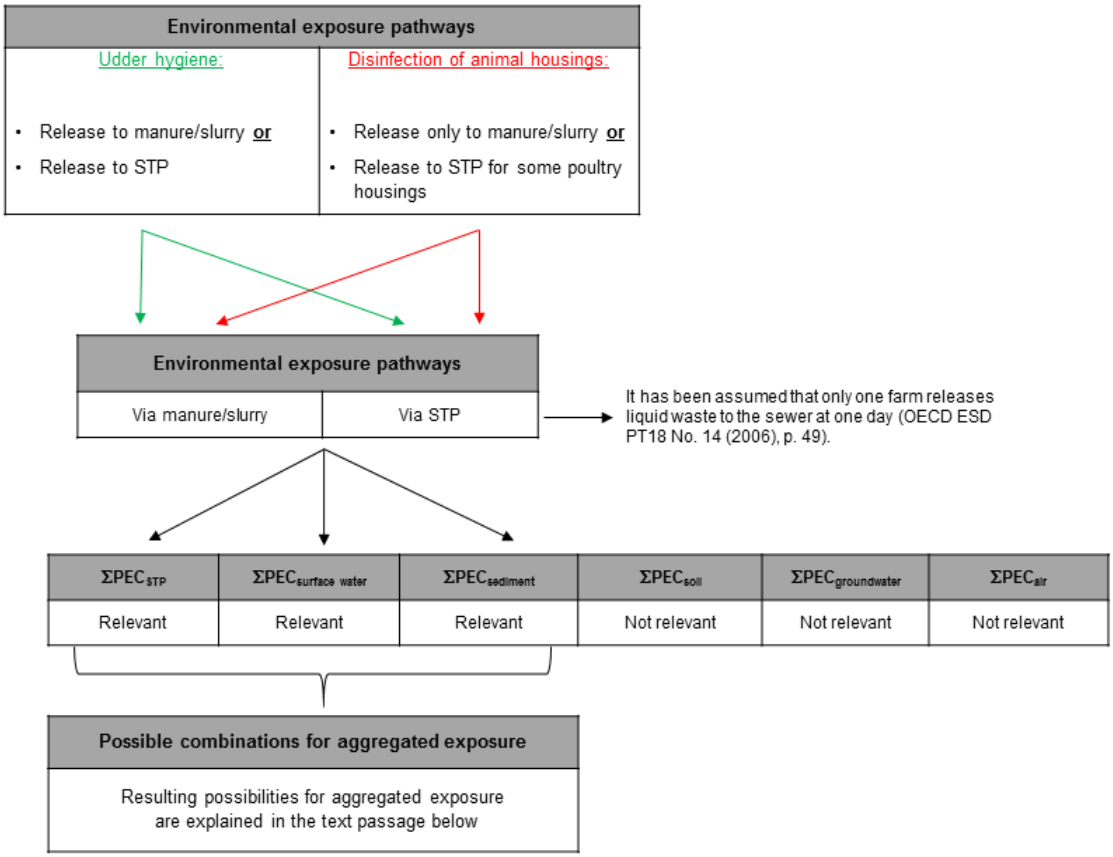

Figure 4: Flow-chart on the selection of the relevant environmental compartments for the aggregated exposure assessment

In total there are three affected environmental compartments:

1) STP: Some of the poultry housings may dispose of a connection to the local sewer system and release therefore waste water to the municipal STP. The RefMS assumes that, if milking parlours are also connected to the local sewer system, waste water from milking parlour might be released to the same STP as from the poultry housing. Thus, an aggregated PEC_{STP} should be derived for these a.s. release to the environmental compartment.
   For the sake of completeness, it should be kept in mind that either a poultry housing or a milking parlour is connected to the municipal STP. An aggregated exposure may then taking into account foremost for the aquatic compartment (see therefore point 2).
2) Surface water: The b.p. can be used for disinfection of animal housings (pigs and poultries) or for teat disinfection of lactating animals. In both cases, releases of a.s. residues to manure must be considered. If the contaminated manure is spread onto agricultural soil, run-off to surface water has to be regarded. Besides, the effluent of STP is discharging to a receiving water. In consequence, one would have to assume that run-off from agricultural soil and discharge of STP effluent can lead to an overlap in time and receiving water space. Thus, the following realistic combination possibilities of a.s. releases to the aquatic compartment (surface water and sediment) should be regarded for aggregated exposure assessment:
   a. Poultry housing and milking parlour are connected to the same STP:
      i. $PEC_{surface\ water,\ STP;total}$ + $PEC_{surface\ water,\ run\text{-}off,\ disinfection\ of\ animal\ housings}$
      ii. $PEC_{surface\ water,\ STP,total}$ + $PEC_{surface\ water,\ run\text{-}off\ teat\ disinfection}$

b. Milking parlour is connected to the STP
   i. $PEC_{surface\ water,\ STP;\ teat\ disinfection}$ + $PEC_{surface\ water,\ run\text{-}off,\ disinfection\ of\ animal\ housings}$
   ii. $PEC_{surface\ water,\ STP,\ teat\ disinfection}$ + $PEC_{surface\ water,\ run\text{-}off,\ teat\ disinfection}$
c. Poultry housing is connected to STP
   i. $PEC_{surface\ water,\ STP;\ disinfection\ of\ poultry\ housings}$ + $PEC_{surface\ water,\ run\text{-}off,\ disinfection\ of\ animal\ housings}$
   ii. $PEC_{surface\ water,\ STP,\ disinfection\ of\ poultry\ housings}$ + $PEC_{surface\ water,\ run\text{-}off,\ teat\ disinfection}$

3) Sediment: For sediment the same assumptions as for surface water apply.

For the sake of clarity, the RefMS decided to present in this PAR only the worst case results from the above summarised combination possibilities. For the BPF "Anti-Germ Iodine Based Disinfectants Product Family" means that with three affected compartments three derived PEC_{agg}:

1) $PEC_{agg,\ STP}$: Both, poultry housing and milking parlour, release the contaminated waste water to the local sewer system
2) $PEC_{agg,\ surface\ water}$: The run-off from agricultural soil (grassland as worst case) is added to the release from an STP where both, poultry housing and milking parlour, are connected to (equates to the combination a.ii.).
3) $PEC_{agg,\ sediment}$: For sediment the same considerations as for $PEC_{agg,\ surface\ water}$ apply.

An overview of the predicted environmental concentrations in STP ($PEC_{agg,\ STP}$), in surface water ($PEC_{agg,\ surface\ water}$) as well as in sediment (PEC_{agg_sed}) resulting from the respective uses are given in the following table:

Table 123: Summary table on calculated $PEC_{aggregated}$ for STP, surface water and sediment

Chemical speciation	$PEC_{agg,\ STP}$ [µg/L]	$PEC_{agg,\ surface\ water}$ [µg/L]	$PEC_{agg,\ sediment}$ [µg/kg]
Iodine	140.36	17.31	842.33
Iodate	194.25	23.88	1161.16
Iodide	140.36	17.31	842.33

- to Part 2:

Besides the approval in PT 3 the a.s iodine is admitted in PT 1, 4 and 22. Even if it is yet no application approval for b.p. in any of the other PTs, in principle it must be assumed that the same a.s./b.p. is used in further PTs . Additionally, more intended uses in PT 3 could be added.
Therefore, there is the possibility that an overlapping of releases to environmental compartments in time and space of iodine containing products can occur.

In case of the same environmental exposure pathways, a summary analogous to part 1 has to be added.

- to Part 3:

The third part of the decision tree seems to be not applicable for iodine. On basis of the current knowledge, no further applications as main constituent in other a.s. are known. Therefore, an overlapping release in time and space could be excluded for the moment.

3.8.5 Risk characterisation for meta SPC 1 to 4

3.8.5.1 *Aquatic compartment and STP*

- **Surface water**

Table 124 Meta SPC 1 - Risk characterisation for surface water

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	via STP	0.204	0.59	0.35
	Iodate		0.281	58.5	0.005
	Iodide		0.204	0.83	0.25
	Iodine	Slurry/manure application on grassland	5.27	0.59	**8.93**
	Iodate		7.26	58.5	0.12
	Iodide		5.27	0.83	**6.35**
	Iodine	Slurry/manure application on arable land	0.96	0.59	**1.63**
	Iodate		1.32	58.5	0.02
	Iodide		0.96	0.83	**1.16**

Table 125 Meta SPC 2 - Risk characterisation for surface water

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	via STP	0.235	0.59	0.4
	Iodate		0.324	58.5	0.006
	Iodide		0.235	0.83	0.28
	Iodine	Slurry/manure application on grassland	6.08	0.59	**10.31**
	Iodate		8.36	58.5	0.14
	Iodide		6.08	0.83	**7.33**
	Iodine	Slurry/manure application on arable land	1.10	0.59	**1.86**
	Iodate		1.52	58.5	0.03
	Iodide		1.10	0.83	**1.33**

Table 126 Meta SPC 3 - Risk characterisation for surface water

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat dipping)	Iodine	via STP	0.139	0.59	0.24
	Iodate		0.192	58.5	0.003
	Iodide		0.139	0.83	0.17
	Iodine	Slurry/manure application on grassland	3.60	0.59	**6.10**
	Iodate		4.96	58.5	0.08
	Iodide		3.60	0.83	**4.34**
	Iodine	Slurry/manure application on arable land	0.65	0.59	**1.10**
	Iodate		0.90	58.5	0.02
	Iodide		0.65	0.83	0.78

Table 127 Meta SPC 4 - Risk characterisation for surface water

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Teat disinfection	Iodine	via STP	0.16	0.59	0.27
	Iodate		0.221	58.5	0.004
	Iodide		0.16	0.83	0.19
	Iodine	Slurry/manure application on grassland	4.14	0.59	**7.02**
	Iodate		5.70	58.5	0.10
	Iodide		4.14	0.83	**4.99**
	Iodine	Slurry/manure application on arable land	0.75	0.59	**1.27**
	Iodate		1.04	58.5	0.02
	Iodide		0.75	0.83	0.90

Conclusion

The PEC/PNEC-ratios for iodine and/or iodide were found to be greater than 1 as a result of the application of slurry/manure on grassland and/or arable land. All other PEC/PNEC-ratios were less than 1 and thus not indicating an unacceptable risk for the surface water compartment, if the products that belong to meta SPC 1 to 4 are used for teat disinfection. Even though the PEC/PNEC-ratios for iodine and iodide exceeded the trigger value of 1, the PEC values are still within the range of the natural background concentrations of iodine in surface waters (0.5 – 20 µg/L). It can therefore be concluded that the use of the products of meta SPC 1 to 4 for teat disinfection does not pose an unacceptable risk to the surface water compartment.

- **STP**

Table 128 Meta SPC 1 - Risk characterisation for the STP

Summary table on calculated PEC/PNEC values				
Intended use	**Chemical speciation**	**PEC [mg/L]**	**PNEC [mg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	0.002	2.9	0.0007

Table 129 Meta SPC 2 - Risk characterisation for the STP

Summary table on calculated PEC/PNEC values				
Intended use	**Chemical speciation**	**PEC [mg/L]**	**PNEC [mg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	0.002	2.9	0.0008

Table 130 Meta SPC 3 - Risk characterisation for the STP

Summary table on calculated PEC/PNEC values				
Intended use	**Chemical speciation**	**PEC [mg/L]**	**PNEC [mg/L]**	**PEC/PNEC**
Teat disinfection (dairy cow teat dipping)	Iodine	0.001	2.9	0.0005

Table 131 Meta SPC 4 - Risk characterisation for the STP

Summary table on calculated PEC/PNEC values				
Intended use	**Chemical speciation**	**PEC [mg/L]**	**PNEC [mg/L]**	**PEC/PNEC**
Teat disinfection	Iodine	0.002	2.9	0.0006

Conclusion

The PEC/PNEC-ratio for the STP was found to be less than 1 and thus not indicating an unacceptable risk to the STP.

3.8.5.2 *Terrestrial compartment (Soil/Groundwater)*

- **Soil**

Table 132 Meta SPC 1 - Risk characterisation for the soil compartment

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/kg$_{ww}$]**	**PNEC [µg/kg$_{ww}$]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	via STP	12.655	11.8	**1.07**
	Iodate		17.441	304	0.06
	Iodide		1.772	4.3	**0.41**
	Iodine	Slurry/manure application on grassland	276.53	11.8	**23.43**
	Iodate		381.12	304	**1.25**
	Iodide		276.53	4.3	**64.31**
	Iodine	Slurry/manure application on arable land	50.24	11.8	**4.26**
	Iodate		69.23	304	0.23
	Iodide		50.24	4.3	**11.68**

Table 133 Meta SPC 2 - Risk characterisation for the soil compartment

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/kg$_{ww}$]**	**PNEC [µg/kg$_{ww}$]**	**PEC/PNEC**
Teat disinfection (dairy cow teat spraying)	Iodine	via STP	14.58	11.8	**1.24**
	Iodate		20.1	304	0.007
	Iodide		2.04	4.3	**0.48**
	Iodine	Slurry/manure application on grassland	318.66	11.8	**27.01**
	Iodate		439.18	304	**1.44**
	Iodide		318.66	4.3	**74.11**
	Iodine	Slurry/manure application on arable land	57.89	11.8	**4.91**
	Iodate		79.78	304	0.26
	Iodide		57.89	4.3	**13.46**

Table 134 Meta SPC 3 - Risk characterisation for the soil compartment

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/kg$_{ww}$]**	**PNEC [µg/kg$_{ww}$]**	**PEC/PNEC**
Teat disinfection (dairy cow teat dipping)	Iodine	via STP	8.65	11.8	0.73
	Iodate		11.92	304	0.04
	Iodide		1.21	4.3	0.28
	Iodine	Slurry/manure application on grassland	189.04	11.8	**16.03**
	Iodate		260.53	304	0.86
	Iodide		189.04	4.3	**43.96**
	Iodine	Slurry/manure application on arable land	34.34	11.8	**2.91**
	Iodate		47.33	304	0.16
	Iodide		34.34	4.3	**7.99**

Table 135 Meta SPC 4 - Risk characterisation for the soil compartment

Summary table on calculated PEC/PNEC values					
Intended use	**Chemical speciation**	**Exposure**	**PEC [µg/kg$_{ww}$]**	**PNEC [µg/kg$_{ww}$]**	**PEC/PNEC**
Teat disinfection	Iodine	via STP	9.94	11.8	0.84
	Iodate		13.66	304	0.05
	Iodide		1.39	4.3	0.32
	Iodine	Slurry/manure application on grassland	217.19	11.8	**18.41**
	Iodate		299.34	304	0.98
	Iodide		217.19	4.3	**50.51**
	Iodine	Slurry/manure application on arable land	39.46	11.8	**3.43**
	Iodate		54.38	304	0.18
	Iodide		39.46	4.3	**9.18**

Conclusion

The risk assessment for the soil compartment revealed that the PEC/PNEC-ratios for iodine related to the exposure via the STP as well as the PEC/PNEC-ratios for iodine and/or iodide related to the application of slurry/manure to grassland and/or arable land exceed the trigger value of 1. However, the corresponding PEC-values are below the natural background concentrations of iodine in soil (0.5 – 20 mg/kg dw) that are given in section 3.8.3. It can therefore be concluded that the use of the products of meta SPC 1 to 4 for teat disinfection does not pose an unacceptable risk to the soil compartment.

- **Groundwater**

For the risk assessment for groundwater, the maximum permissible concentration for pesticides laid down in by Directive 98/83/EC is usually applied. According to the definition of “pesticide” in Regulation 98/83/EG, the limit value of 0.1 µg/L applies for organic compounds and relevant metabolites or breakdown or reaction products, respectively. Based on this definition iodine, iodide as well as iodate are not within the scope of this Directive and the trigger value of 0.1 µg/L is not applicable for a quantitative risk assessment of iodine. Thus, a qualitative risk assessment for groundwater is performed by comparing the PECs for groundwater with the natural background concentration of iodine.

For the use as a teat disinfectant, the following PEC_{GW}-values were estimated:

- Meta SPC 1: up to 52.8, 72.8 and 52.8 µg/L for iodine, iodate and iodide, respectively
- Meta SPC 2: up to 60.9, 83.9 and 60.9 µg/L for iodine, iodate and iodide, respectively
- Meta SPC 3: up to 36.1, 49.8 and 36.1 µg/L for iodine, iodate and iodide, respectively
- Meta SPC 4: up to 41.5, 57.2 and 41.5 µg/L for iodine, iodate and iodide, respectively

Since these values are within the range of the natural background concentration for iodine as described in section 3.8.3, no unacceptable risk for the groundwater compartment can be assumed.

3.8.5.3 *Aggregated risk assessment*

Table 136 Aggregated risk assessment

Summary table PEC/PNEC values for aggregated rsik assessment				
Chemical speciation	**Compartment**	**PEC_{agg} [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Iodine	STP	140.36	2900	0.05
Iodine	Surface water	17.31	0.59	**29.3**
Iodate		23.88	58.5	0.41
Iodide		17.31	0.83	**20.9**
Chemical speciation	**Compartment**	**PEC_{agg} [µg/kg]**	**PNEC [µg/kg]**	**PEC/PNEC**
Iodine	Sediment	842.33	29	**29.0**
Iodate		1161.16	2840	0.41
Iodide		842.33	43	**19.6**

In the aggregated risk assessment PEC/PNEC-ratios of up to 29.3 for surface water and 29.0 for sediment were determined. The exceedance of the trigger value of 1 generally indicates an unacceptable risk for the environment. However, the estimated PECs for the respective compartments are still within the range of the natural background concentrations for iodine in the environment. Furthermore, for the aggregated exposure assessment the simultaneous release of iodine from all uses in all meta SPCs of the BPF was assumed, which in turn can be considered a worst-case assumption.

In consideration of the before mentioned aspects, it can thus be concluded that no negative effects in the environment related to the use of the biocidal products belonging to the BPF are to be expected.

3.8.5.4 *Atmosphere*

As stated in section 3.8.2.3 the release of iodine from the intended uses of meta SPCs 1 to 4 can be considered to be negligible for the atmosphere.

3.8.5.5 *Non-compartment specific effects*

As described in section 3.8.2.4 the amounts of iodine potentially released into the environment through biocidal uses are within the natural background levels. Thus, there is no concern with regard to non-compartment specific effects that may result from the use of the products that belong to meta SPCs 1 to 4.

3.8.5.6 *PBT assessment*

According to Annex XIII of Regulation (EG) 1907/2006 the criteria for PBT assessment are not applicable to iodine.

3.8.5.7 *Endocrine disrupting properties*

According to the CAR for the a.s., iodine is an essential element for the thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both iodine deficiency as well as an excess of iodine can impair thyroid homeostasis/thyroid hormone levels. Although, this can be considered as an endocrine effect, it does not justify the conclusion that iodine needs to be considered as an endocrine disruptor.

3.8.5.8 *Summary of risk characterisation*

In consideration of the risk assessment for all relevant environmental compartments, it can be concluded that the use of the biocidal products belonging to meta SPCs 1 to 4 of the BPF does not result in unacceptable risks for the environment.

3.8.6 Risk characterisation for meta SPC 5

3.8.6.1 *Aquatic compartment and STP*

- **Surface water**

Table 137 Risk characterisation for surface water

	Summary table on calculated PEC/PNEC values						
Intended use	**Livestock**	**Release to**	**Exposure scenario**	**Chemical Speciation**	**PEC [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Disinfection of animal houses	Turkeys	Waste water	via STP	Iodine	11.0	0.59	**18.64**
				Iodate	15.2	58.5	0.26
				Iodide	11.0	0.83	**13.25**
	Sows in individual pens	Slurry/manure	Grassland	Iodine	4.01	0.59	**6.80**
				Iodate	5.53	58.5	0.09
				Iodide	4.01	0.83	**4.83**
	Ducks	Slurry/manure and waste water		Iodine	4.17	0.59	**7.07**
				Iodate	5.74	58.5	0.10
				Iodide	4.17	0.83	**5.02**
	Sows in individual pens	Slurry/manure	Arable land	Iodine	2.42	0.59	**4.10**
				Iodate	3.33	58.5	0.07
				Iodide	2.42	0.83	**2.92**
	Ducks	Slurry/manure and waste water		Iodine	2.51	0.59	**4.25**
				Iodate	3.46	58.5	0.06
				Iodide	2.51	0.83	**3.02**

Conclusion

The PEC/PNEC-ratios for iodine and iodide related to the exposure via the STP as well as the PEC/PNEC-ratios for iodine and iodide related to the application of slurry/manure to grassland and arable land exceed the trigger value of 1. All other PEC/PNEC-ratios were less than 1 and thus not indicating an unacceptable risk for the surface water compartment, if the products that belong to meta 5 are used for the disinfection of animal houses. Even though the PEC/PNEC-ratios for iodine and iodide exceeded the trigger value of 1, the PEC values are still within the range of the natural background concentrations of iodine in surface waters (0.5 – 20 µg/L). It can therefore be concluded that the use of the products of meta SPC 5 for the disinfection of animal houses does not pose an unacceptable risk to the surface water compartment.

- **STP**

Table 138 Risk characterisation for the STP

Summary table on calculated PEC/PNEC values				
Intended use	**Chemical speciation**	**PEC [mg/L]**	**PNEC [mg/L]**	**PEC/PNEC**
Disinfection of animal houses	Iodine	0.138	2.9	0.05

Conclusion

The PEC/PNEC-ratio for the STP was found to be less than 1 and thus not indicating an unacceptable risk to the STP.

3.8.6.2 *Terrestrial compartment (Soil/Groundwater)*

- **Soil**

Table 139 Risk characterisation for the soil compartment

Summary table on calculated PEC/PNEC values							
Intended use	**Livestock**	**Release to**	**Exposure scenario**	**Chemical Speciation**	**PEC [µg/kg$_{ww}$]**	**PNEC [µg/kg$_{ww}$]**	**PEC/PNEC**
Disinfection of animal houses	Turkeys	Waste water	via STP	Iodine	685	11.8	**58.0**
				Iodate	944	304	**3.1**
				Iodide	95.8	4.3	**22.3**
	Sows in	Slurry/manure	Grassland	Iodine	231	11.8	**19.6**

	individual pens			Iodate	319	304	**1.05**
				Iodide	231	4.3	**53.7**
	Ducks	Slurry/manure and waste water		Iodine	240	11.8	**20.3**
				Iodate	331	304	**1.09**
				Iodide	240	4.3	**55.8**
	Sows in individual pens	Slurry/manure	Arable land	Iodine	139	11.8	**11.78**
				Iodate	192	304	0.63
				Iodide	139	4.3	**32.3**
	Ducks	Slurry/manure and waste water		Iodine	145	11.8	**12.3**
				Iodate	199	304	0.65
				Iodide	145	4.3	**33.7**

Conclusion

Except for iodate related to the application of “slurry/manure” or “slurry/manure and waste water” to arable land all PEC/PNEC-ratios were found to be greater than the trigger value of 1. However, the corresponding PEC-values are below the natural background concentrations of iodine in soil (0.5 – 20 mg/kg dw) that are given in section 3.8.3. It can therefore be concluded that the use of the products of meta SPC 5 for the disinfection of animal houses does not pose an unacceptable risk to the soil compartment.

- **Groundwater**

For the risk assessment for groundwater, the maximum permissible concentration for pesticides laid down in by Directive 98/83/EC is usually applied. According to the definition of “pesticide” in Regulation 98/83/EG, the limit value of 0.1 µg/L applies for organic compounds and relevant metabolites or breakdown or reaction products, respectively. Based on this definition iodine, iodide as well as iodate are not within the scope of this Directive and the trigger value of 0.1 µg/L is not applicable for a quantitative risk assessment of iodine. Thus, a qualitative risk assessment for groundwater is performed by comparing the PECs for groundwater with the natural background concentration of iodine.

For the biocidal products of meta SPC 5 that are used for the disinfection of stables, PEC_{GW}-values of up to 128.5, 176.6 and 27.6 µg/L for iodine, iodate and iodide, respectively, were estimated. The PEC_{GW}-values for iodine and iodate are above the average natural background concentrations that are stated in section 3.8.3, but are still below the reported natural maximum concentrations of up to 400 µg/L. By assessing the potential risk for the groundwater compartment it must also be taken in mind, that the PEC_{GW}-values are the result of a tier 1 exposure assessment and represent worst case concentrations. It is therefore to be expected that the iodine concentrations in groundwater will be significantly below the estimated PEC_{GW}-values under field conditions. Consequently, no unacceptable risks for groundwater related to the intended use of the biocidal products of meta SPC 5 are expected.

3.8.6.3 *Aggregated risk assessment*

Table 140 Aggregated risk assessment

Summary table PEC/PNEC values for aggregated rsik assessment				
Chemical speciation	**Compartment**	**PEC_{agg} [µg/L]**	**PNEC [µg/L]**	**PEC/PNEC**
Iodine	STP	140.36	2900	0.05
Iodine	Surface water	17.31	0.59	**29.3**
Iodate		23.88	58.5	0.41
Iodide		17.31	0.83	**20.9**
Chemical speciation	**Compartment**	**PEC_{agg} [µg/kg]**	**PNEC [µg/kg]**	**PEC/PNEC**
Iodine	Sediment	842.33	29	**29.0**
Iodate		1161.16	2840	0.41
Iodide		842.33	43	**19.6**

In the aggregated risk assessment PEC/PNEC-ratios of up to 29.3 for surface water and 29.0 for sediment were determined. The exceedance of the trigger value of 1 generally indicates an unacceptable risk for the environment. However, the estimated PECs for the respective compartments are still within the range of the natural background concentrations for iodine in the environment. Furthermore, for the aggregated exposure assessment the simultaneous release of iodine from all uses in all meta SPCs of the BPF was assumed, which in turn can be considered a worst-case assumption.

In consideration of the before mentioned aspects, it can thus be concluded that no negative effects in the environment related to the use of the biocidal products belonging to the BPF are to be expected.

3.8.6.4 *Atmosphere*

As stated in section 3.8.2.3 the release of iodine from the intended uses of meta SPC 5 can be considered to be negligible for the atmosphere.

3.8.6.5 *Non-compartment specific effects*

As described in section 3.8.2.4 the amounts of iodine potentially released into the environment through biocidal uses are within the natural background levels. Thus, there is no concern with regard to non-compartment specific effects that may result from the use of the products that belong to meta SPC 5.

3.8.6.6 *PBT assessment*

According to Annex XIII of Regulation (EG) 1907/2006 the criteria for PBT assessment are not applicable to iodine.

3.8.6.7 *Endocrine disrupting properties*

According to the CAR for the a.s., iodine is an essential element for the thyroid hormone synthesis (i.e. intentionally interacts with the endocrine system). This means that both iodine deficiency as well as an excess of iodine can impair thyroid homeostasis/thyroid hormone levels. Although, this can be considered as an endocrine effect, it does not justify the conclusion that iodine needs to be considered as an endocrine disruptor.

3.8.6.8 *Summary of risk characterisation*

In consideration of the risk assessment for all relevant environmental compartments, it can be concluded that the use of the biocidal products belonging to meta SPC 5 of the BPF does not result in unacceptable risks for the environment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified; hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

Table 141

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.1. Appearance (at 20 °C and 101,3 kPa)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY	15-909024-017	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.1. Appearance (at 20 °C and 101,3 kPa)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY-27	15-909024-002	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.1. Appearance (at 20 °C and 101,3 kPa)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-BAR	15-909024-023	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.1. Appearance (at 20 °C and 101,3 kPa)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-FILM-27	15-909024-007	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.1. Appearance (at 20 °C and 101,3 kPa)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY-27	15-909024-012	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.1. Appearance (at 20 °C and 101,3 kPa)	Accelerated storage stability test at 30°C ± 2°C for 20 weeks on Germicidan IODES	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.2. Acidity/alkalinity	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-SPRAY	No.15-909024-020	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.2. Acidity/alkalinity	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-SPRAY-27	No.15-909024-005	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.2. Acidity/alkalinity	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-BAR	No.15-909024-026	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.2. Acidity/alkalinity	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-FILM-27	No.15-909024-010	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.2. Acidity/alkalinity	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-BAR-27	No.15-909024-015	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.2. Acidity/alkalinity	Accelerated storage stability test at 30°C ± 2°C for 20 weeks on Germicidan IODES	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on ANTI-GERM IO-SPRAY	No.15-909024-016	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on ANTI-GERM IO-SPRAY-27	No.15-909024-001	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on ANTI-GERM IO-BAR	No.15-909024-022	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on ANTI-GERM IO-FILM-27	No.15-909024-006	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on ANTI-GERM IO-BAR-27	No.15-909024-011	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.3. Relative density (liquids) and bulk, tap density (solids)	Physico-chemical tests on Germicidan IODES	AT 09.02.05	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.1. Accelerated storage test	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-SPRAY	No.15-909024-020	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.1. Accelerated storage test	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-SPRAY-27	No.15-909024-005	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.4.1.1. Accelerated storage test	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-BAR	No.15-909024-026	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.1. Accelerated storage test	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-FILM-27	No.15-909024-010	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.1. Accelerated storage test	Physico-chemical tests and chemical analyses before, during and after an accelerated storage procedure at 30 ± 2°C for 18 weeks on ANTI-GERM IO-BAR-27	No.15-909024-015	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.1. Accelerated storage test	Accelerated storage stability test at 30°C ± 2°C for 20 weeks on Germicidan IODES	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY	No.15-909024-021	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY	No.15-909024-021	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6, 12 and 18 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY	No.15-909024-021	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY-27	No.15-909024-028	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY-27	No.15-909024-028	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6, 12 and 18 months of storage at 20 ± 2 °C on ANTI-GERM IO-SPRAY-27	No.15-909024-028	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR	No.15-909024-027	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR	No.15-909024-027	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6, 12 and 18 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR	No.15-909024-027	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-FILM-27	No.15-909024-029	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-FILM-27	No.15-909024-029	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6, 12 and 18 months of storage at 20 ± 2°C on ANTI-GERM IO-FILM-27	No.15-909024-029	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR-27	No.15-909024-030	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6 and 12 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR-27	No.15-909024-030	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	Physico-chemical tests and chemical analyses after 6, 12 and 18 months of storage at 20 ± 2°C on ANTI-GERM IO-BAR-27	No.15-909024-030	Demangel, B.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	STUDY - PROTOCOL GERMICIDAN IODES LONG TERM STORAGE TEST AT AMBIENT TEMPERATURE 24 MONTHS AT ROOM TEMPERATURE	AT 09.02.03	Mayer, P.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.2. Long term storage test at ambient temperature	STUDY - PROTOCOL GERMICIDAN IODES LONG TERM STORAGE TEST AT AMBIENT TEMPERATURE 24 MONTHS AT ROOM TEMPERATURE	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.4.1.2. Long term storage test at ambient temperature	STUDY - PROTOCOL GERMICIDAN IODES LONG TERM STORAGE TEST AT AMBIENT TEMPERATURE 24 MONTHS AT ROOM TEMPERATURE - Intermediate Report after 18 months of storage	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY	15-909024-017	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY-27	15-909024-002	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-BAR	15-909024-023	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-FILM-27	15-909024-007	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 7 days at 0 ± 2°C on ANTI-GERM IO-SPRAY-27	15-909024-012	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.4.1.3. Low temperature stability test (liquids)	Physico-chemical tests after low temperature storage procedure for 14 days at 0°C ± 2°C on Germicidan IODES	AT 09.02.02	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.5.7. Persistent foaming	Physico-chemical tests on Germicidan IODES	AT 09.02.05	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.7. Degree of dissolution and dilution stability	Accelerated storage stability test at 30°C ± 2°C for 20 weeks on Germicidan IODES	AT 09.02.01	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on ANTI-GERM IO-SPRAY	No.15-909024-016	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on ANTI-GERM IO-SPRAY-27	No.15-909024-001	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on ANTI-GERM IO-BAR	No.15-909024-022	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on ANTI-GERM IO-FILM-27	No.15-909024-006	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on ANTI-GERM IO-BAR-27	No.15-909024-011	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.8. Surface tension	Physico-chemical tests on Germicidan IODES	AT 09.02.05	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
3.9. Viscosity	Physico-chemical tests on ANTI-GERM IO-SPRAY	No.15-909024-016	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.9. Viscosity	Physico-chemical tests on ANTI-GERM IO-SPRAY-27	No.15-909024-001	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
3.9. Viscosity	Physico-chemical tests on ANTI-GERM IO-BAR	No.15-909024-022	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.9. Viscosity	Physico-chemical tests on ANTI-GERM IO-FILM-27	No.15-909024-006	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.9. Viscosity	Physico-chemical tests on ANTI-GERM IO-BAR-27	No.15-909024-011	Demangel, B.	2015	ANTI-GERM International GmbH, Memmingen, Germany
3.9. Viscosity	Physico-chemical tests on Germicidan IODES	AT 09.02.05	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
4.16. Corrosive to metals	Analytical Results	AQ066-16	Rodriguez, N.	2016	ANTI-GERM International GmbH, Memmingen, Germany
4.16. Corrosive to metals	Analytical Results	AQ076-16	Rodriguez, N.	2016	ANTI-GERM International GmbH, Memmingen, Germany
4.16. Corrosive to metals	Determination of the corrosion of metals by ANTI-GERM IO-SPRAY 27 following method 37.4 C.1 of the UN Handbook sixth revised edition, UN, 2015	17012703N979	Krebs, F.	2017	ANTI-GERM International GmbH, Memmingen, Germany
4.6. Flammable liquids	FLASH POINT: ANTI-GERM IODACID, FLASH POINT: GERMICIDAN IODES	ISP-NG-2015-1	Schütz, S.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine ANTI-GERM IO-SPRAY	No.15-909024-018	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine ANTI-GERM IO-SPRAY-27	No.15-909024-003	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine ANTI-GERM IO-BAR	No.15-909024-024	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine ANTI-GERM IO-FILM-27	No.15-909024-008	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine ANTI-GERM IO-BAR-27	No.15-909024-013	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodine in Germicidan IODES	AT 09.02.04	Mayer, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodide and iodate in ANTI-GERM IO-SPRAY	No.15-909024-019	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodide and iodate ANTI-GERM IO-SPRAY-27	No.15-909024-004	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodide and iodate in ANTI-GERM IO-BAR	No.15-909024-025	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodide and iodate in ANTI-GERM IO-FILM-27	No.15-909024-009	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
5.1. Analytical method […]	Validation of the analytical method for the determination of iodide and iodate in ANTI-GERM IO-BAR-27	No.15-909024-014	Ricau, H.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°429/1113-1/A/M1	429/1113-1/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
6.7. Efficacy data […]	TEST REPORT N°429/1113-2/A/M1	429/1113-2/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°429/1113-4/A/M1	429/1113-4/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°429/1113-5/A/M1	429/1113-5/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Test Report N°RE-1122/0716	1122/0716	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the bactericidal activity of the product « ANTI-GERM® IO-SPRAY-27 » - NF EN 1656 (March 2010) - Bactericidal activity for teat disinfection - Obligatory conditions -	B15-00020C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the yeasticidal activity of the product « ANTI-GERM® IO-SPRAY-27 » - NF EN 1657 (April 2006) methodology - Yeasticidal activity for teat disinfection	BC15-00029C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT NRE-1082/0716-1	1082/0716-1	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°428/1113-1/A/M1	428/1113-1/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°428/1113-2/A/M1	428/1113-2/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
6.7. Efficacy data […]	Test Report N°RE-1121/0716	1121/0716	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the bactericidal activity of the product « ANTI-GERM® IO-FILM-27 » - NF EN 1656 (March 2010) - Bactericidal activity for teat disinfection - Obligatory conditions -	B15-00021C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the yeasticidal activity of the product « ANTI-GERM® IO-FILM-27 » - NF EN 1657 (April 2006) methodology - Yeasticidal activity for teat disinfection	BC15-00030C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Test Report N°RE 1119/0716	1119/0716	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Test Report N°RE 1102/0217	1102/0217	Carre, A.; Strohl, P.	2017	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°427/1113-1/A/M1	427/1113-1/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	TEST REPORT N°427/1113-2/A/M1	427/1113-2/A/M1	Strohl, P.	2013	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the yeasticidal activity of the product « ANTI-GERM® IO-BAR » - NF EN 1657 (April 2006) methodology - Yeasticidal activity for teat disinfection	BC15-000101C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Test Report N° RE-1120/0716	1120/0716	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany

Data set according to Annex III Regulation (EU) No 528/2012	Title	Report No.	Author(s)	Year	Owner company
6.7. Efficacy data […]	Determination of the bactericidal activity of the product « ANTI-GERM® IO-BAR-27 » - NF EN 1656 (March 2010) - Bactericidal activity for teat disinfection - Obligatory conditions -	B15-00022C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Determination of the yeasticidal activity of the product « ANTI-GERM® IO-BAR-27 » - NF EN 1657 (April 2006) methodology - Yeasticidal activity for teat disinfection	BC15-00031C	Thery, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Test Report N°RE11118/0716	1118/0716	Strohl, P.	2016	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Quantitative suspension test for the evaluation of bactericidal activity of GERMICIDAN IODES in the veterinary area (DIN EN 1656:2009; Phase 2, Step 1)	L15/0421.1	Brill, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of GERMICIDAN IODES in veterinary area according to DIN EN 1657:2005 (Phase 2, step 1)	L15/0421.10	Brill, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Quantitative surface test for the evaluation of bactericidal activity of GERMICIDAN IODES in the veterinary area (DIN EN 14349:2012; Phase 2, Step 2)	L15/0421.4	Brill, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of GERMICIDAN IODES in veterinary area according to DIN EN 16438:2014 (Phase 2, step 2)	L15/0421.11	Brill, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany
6.7. Efficacy data […]	Evaluation of the effectiveness of GERMICIDAN IODES, Method: EN 14675:2015	A15L0414bE	Brill, F.	2015	ANTI-GERM International GmbH, Memmingen, Germany

4.2 List of studies for the active substance(s)

4.2.1 Iodine

The applicant has access to the data from the active substance approval. No new data was submitted. Please, refer to the corresponding Assessment Report for a reference list.

4.3 Output tables from human health exposure assessment tools

4.3.1 Overview of professional exposure

Zusammenfassung_Expo.pdf

4.3.2 Teat disinfection - Dipping or Foaming

Teat_disinfection_dipping&foamimg.pdf

loading&dipping&foaming_consexpo.pdf

4.3.3 Teat disinfection - Manual spraying by trigger sprayer

Teat_disinfection_manual_spraying_trigge

loading&manual_spraying_triggersprayer_

4.3.4 Teat disinfection – Manual spraying by electronic sprayer

Teat_disinfection_manual_spraying_electr

4.3.5 Teat disinfection - Spraying by robot

Teat_disinfection_spraying_robot.pdf

4.3.6 Disinfection of animal houses - Manual spraying


Animal_house_disinfection_2%.pdf


Animal_house_disinfection_2%_ConsExp

4.3.7 Livestock exposure assessment


Livestock exposure_WCCE_EU a


Livestock exposure_WCCE_natic

5 Confidential annex (Access level: Restricted to applicant and authorities)

Please refer to the separate document.