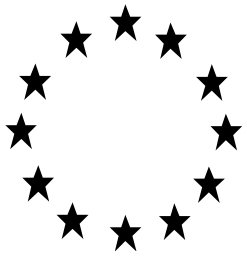
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the eCA)



Iodine based products – CID LINES NV

Product types: PT3, PT4

Active substance names: Iodine and PVP-Iodine

Case Number in R4BP: BC-BY019142-30

Evaluating Competent Authority: CTGB

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1 CONCLUSION

The outcome of the assessment of the 'Iodine based products – CID LINES NV' is specified in the BPC opinion following discussions at the BPC-33 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

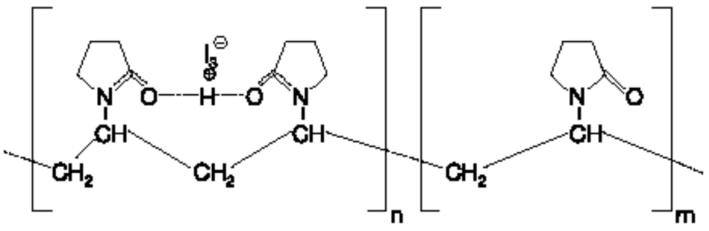
2 ASSESSMENT REPORT

2.1 SUMMARY

2.1.1. Presentation of the biocidal product family

A. IDENTITY OF THE ACTIVE SUBSTANCES

Main constituent(s): IODINE	
ISO name	No ISO common name available
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	>99.5%
Structural formula	I-I

Main constituent(s): PVP-Iodine	
ISO name	No ISO common name available
IUPAC or EC name	Polyvinylpyrrolidone iodine
EC number	-
CAS number	25655-41-8
Index number in Annex VI of CLP	PVP-iodine releases the active substance iodine for which the index number in annex VI of CLP is 053-001-00-3.
Minimum purity / content	PVP-iodine contains 9 – 12% iodine
Structural formula	

B. PRODUCT FAMILY COMPOSITION AND FORMULATION

Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%w/w)	
					Min	Max
Iodine / PVP - Iodine	Iodine	Active substance	7553-5 6-2	231-442-4	0.0	3.0
	PVP-Iodine	Active substance	25655-41-8	-	0	10.0 (1.2% Iodine)
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	0	21.0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3	-	0	12.5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0	30.0

According to the pharmacopoeia, PVP-iodine contains 9 – 12% iodine by mass and up to 6% iodide. See also section 3.4 of the confidential annex for more information on total iodine calculations.
Total iodine is calculated based on the iodine from all iodine sources within the product. See confidential attachment for more information (section 3.4).

Information on the substance(s) of concern

SoCs are mentioned in the table above. See also the confidential annex for more considerations with regard to the SoCs in this product family.

Information on Endocrine disruption

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). It means that an ED hazard assessment should be included in the PAR. Applicants should perform screening for co-formulants contained in the product, and where an alert is identified, perform further ED evaluation. The screening and/or evaluation should be carried out in accordance with the EFSA/ECHA ED guidance (http://www.efsa.europa.eu/en/press/news/180607).

Detailed information on e.g. how a screening was performed for co-formulant(s) if an alert for ED property is found, information type and source from which the alert was found, the outcome of further ED assessment, and the conclusion of the eCA are included in:

- "Others" in section A "Assessment of effects" for human health aspect
- "Further Ecotoxicological studies" in section 2.3 A"Effects assessment on the

environment" for environment aspect
• Confidential Annex can be used in case the ED assessment contains confidential information.

C. AUTHORISED USE(S)

Table 1: Use # 1.1 – *meta* SPC 1: PT3 – Concentrated Teat disinfectants, post-milking, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast and viruses
Field of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By manual or automatic spraying on teats
Application rate(s) and frequency	Dilute the product to a final concentration of 0.3% (w/w) available iodine Apply 2 times per day with manual sprayer and 3 times per day with a robot.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 1.1

The product must be diluted before use
with clean potable water to allow
a final concentration of iodine of 0.3% (200 ml product, add water up to 1L).
Do not prepare more fluid than necessary. Assume 5 mL diluted product per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended. Use gloves and eye protection during the dilution step. The diluted product can be kept and used during 1 week but do not prepare more fluid than necessary. Assume 5 mL per cow per treatment .
The diluted product must be brought to a temperature above 20°C before use.
Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer.
The product should be used directly after milking 2 times per day by using a manual sprayer and 3 times per day when using a robot (automatic sprayer).
Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats.To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
Do not mix with other chemicals.

RISK MITIGATION MEASURES; USE # 1.1

- For mixing an loading of the product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection.

- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 2: Use # 2.1 – *meta* SPC2: PT3 – RTU Teat disinfectants, post-milking, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, viruses
Field of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 2.1

Apply the product by dipping or by spraying:
-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use
-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
For professional use only. Do not mix with other chemicals.

RISK MITIGATION MEASURES; USE # 2.1

- For manual spraying application: Wear chemical resistant gloves (material to be

specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 3: Use # 3.1 – *meta* SPC 3: PT3 – Udder disinfectants, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Skin disinfection only for use on intact skin of: -the udder of dairy and beef cattle on the udder before calving -the udder of sows before farrowing
Application method(s)	By spraying
Application rate(s) and frequency	The product is ready to use. Apply to: -the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4.8 mL per application) -the udder of sows: 15 to 20 ml per animal
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 3.1

For disinfection of the skin:
The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
Apply by spraying on the animals' skin (intact) for a topical disinfection:
- dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
- sows on the udder before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).

Only for use on intact skin.

Do not mix with other chemicals.

RISK MITIGATION MEASURES; USE # 3.1

For manual spraying application on cows and sows: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information). Keep out of reach of children.

Table 4: Use # 4.1 – *meta* SPC 4: PT3 – RTU Teat disinfectants, Post-milking, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast and virus
Field of use	Indoor Ready to use teat disinfectant to be used post milking on milk producing animals.
Application method(s)	Application on teats: by dipping or spraying
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 4.1

For disinfection of the teats:
The product must be brought to a temperature above 20°C before use.
- By dipping: Apply the product on the teats with a dip cup. Wash the dip cup with water after use.
- By spraying: Apply the product on the teats with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended.
The product should be used directly after milking by using a dipping cup or a manual or automatic sprayer. Ensure that the teat is completely covered to three quarters of its length.
The product is applied after milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.

Let the product dry on the teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
Do not mix with other chemicals.

USE SPECIFIC RISK MITIGATION MEASURES; USE # 4.1

- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 5: Use # 4.2 – *meta* SPC 4: PT3 – Udder disinfectants, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Ready to use skin disinfectant only for use on intact skin of: -the udder of dairy and beef cattle before calving -the udder of sows before farrowing
Application method(s)	Application on animal skin: by spraying
Application rate(s) and frequency	The product is ready to use. Apply to: -the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4.8 mL per application) -the udder of sows: Assume 15 to 20 mL per animal
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 4.2

For disinfection of the skin:
The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
Apply by spraying on the animals' skin (intact) for a topical disinfection:
dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact time, care should be taken that the

product is not removed after application (e.g. keep the animal standing at least 5 minutes).
sows on the udder before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).Let the product dry on skin.
Only for use on intact skin.

Do not mix with other chemicals.

USE SPECIFIC RISK MITIGATION MEASURES; USE # 4.2

- For manual spraying application on cows and sows: no PPE is necessary for safe use.
- Keep out of reach of children.

Table 6: Use # 5.1 – *meta* SPC 5: PT3 – RTU Teat disinfectants, Post-milking, PVP-Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, viruses
Field of use	Indoor Post-milking disinfection on teats of milk producing animals
Application method(s)	By spraying or dipping on teats.
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 5.1

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
Apply the product by dipping or by spraying:
-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use
-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.
Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The use of a dosing pump for manual loading is recommended.

The product should be used immediately after each milking: two times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.

Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
Do not mix with other chemicals.

RISK MITIGATION MEASURES; USE # 5.1

- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 7: Use 6.1 – *meta* SPC 6: PT3 – Udder disinfectants, PVP-Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Ready to use skin disinfectant only for use on intact skin of: -the udder of dairy and beef cattle before calving -sows before farrowing
Application method(s)	Application on animal skin: by spraying
Application rate(s) and frequency	The product is ready to use. Apply to: - the udder of dairy and beef cattle: 1 spray on each teat (equivalent to 4.8 mL per application) - the udder of sows: 15 to 20 mL per animal
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE 6.1

The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
Dairy and *beef cattle: Apply the product by spraying on the udder before calving (1 spray / teat equivalent to 4.8 mL per* application). Disinfection takes place once, one day before calving and once, one day after calving. To ensure sufficient contact

time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).- Sows on the udder before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).

Only for use on intact skin.

Do not mix with other chemicals

RISK MITIGATION MEASURES; USE # 6.1

- For manual spraying application on cows and sows: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- Keep out of reach of children.

Table 8: Use # 7.1 – *meta* SPC 7: PT4– Concentrated Surface disinfectants, Iodine

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria and yeasts
Field of use	Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Assume 0.04L solution for every square meter that has to be disinfected. Bactericidal & Yeasticidal activity: 0.015% iodine. Frequency is once per day.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 7.1

Use in professional kitchens (PT04) and in food industry (PT04):

The product is diluted before use (according to the table below).

Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.

The product is used in professional kitchens (surface disinfection): Frequency is once

per day.
The product is used in food industry (surface disinfection): Frequency is once per day. Use at room temperature. Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 15 minutes and rinse the surfaces afterwards with clean water.

Example* for product with 1% iodine	Dilution of the product	Contact time
Bactericidal & Yeasticidal activity	1.5% *(15 ml product, add water up to 1L)*	15 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 1.8% to 2.49% it is not possible to give all product dilutions here.

Do not mix with other chemicals.
Do not prepare more fluid than necessary.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 7.1

- During pouring of the concentrated product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During pumping of the product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information).
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

Table 9: Use # 7.2 – *meta* SPC 7: PT3– Concentrated Surface disinfectants Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast and viruses
Field of use	Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	. . Assume 0.04L solution for every square meter that has to be disinfected. Bactericidal & Yeasticidal activity: 0.025% in-use iodine Virucidal activity: 0.035% in-use iodine
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 7.2

Use in veterinary field (PT3), Surface disinfection:

Product should be diluted with water before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used to disinfect animal housings of pigs, cows and poultry.
Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 30 minutes. Animal housing must be empty of animals during application and re-entry of animals can be done 24h after the end of the application.

Example* for product with 2.49% iodine	Dilution of the product	Contact time
Bactericidal & Yeasticidal activity	**1% (10ml product, add water up to 1L)*	30 min
Virucidal activity	1.4*% (14ml product, add water up to 1L)*	30 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 1.8 to 2.49% it is not possible to give all product dilutions here.

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 7.2

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall (material to be specified by the authorisation holder within the product information)and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product (glove and coverall material to be specified by the authorisation holder within the product information).
- Only use one kind of Iodine-containing product per day.
- Due to potential concern for human health the professionals must not carry out animal house disinfection more than 3 times per months. These professionals should not use Iodine products for additional purposes.
- Due to potential concern for animal health, stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

Table 10: Use # 8.1 – *meta* SPC 8: PT4 – Concentrated Surface disinfectants, Iodine

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria and yeast
Field of use	Non-porous surface disinfection in professional kitchens and in food industry
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Bactericidal & Yeasticidal activity: 0.015% iodine Assume 0.04L solution for every square meter that has to be disinfected. Frequency is once per day.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 8.1

- <u>Use in professional kitchens (PT04) and in food industry (PT04):</u>

The product is diluted before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used in professional kitchens (surface disinfection): Frequency is once per day.

The product is used in food industry (surface disinfection): Frequency is once per day. Use at room temperature. The product is applied by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 15 minutes and rinse the surfaces afterwards with clean water.

Example* for product with 3% iodine	Dilution of the product	Contact time
Bactericidal & Yeasticidal activity	*0.5% (5 ml product, add water up to 1L)*	15 min

*Each product label should give information on how the dilution should be made. Since the concentration iodine in products within this meta SPC can range from 2.5 to 3% it is not possible to give all product dilutions here.

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 8.1

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall (material to be specified by the authorisation holder within the product information) and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and coverall material to be specified by the authorisation holder within the product information) and eye/face protection.
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

Table 11: Use # 8.2 – *meta* SPC 8: PT3 – Concentrated Surface disinfectants Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeast, viruses
Field of use	Non-porous surface disinfection in veterinary field
Application method(s)	By spraying with a manual or an automatic sprayer
Application rate(s) and frequency	Bactericidal & Yeasticidal activity: 0.025% in-use iodine Virucidal activity: 0.035% in-use iodine Assume 0.04L solution for every square meter that has to be disinfected.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

USE-SPECIFIC INSTRUCTIONS FOR USE; USE # 8.2

Use in veterinary field (PT3), Surface disinfection:
Product should be diluted with water before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used to disinfect animal housings of pigs, cows and poultry.
Apply the product by spraying with a manual or an automatic sprayer. Make sure to wet the surface completely. Allow to take effect for at least 30 minutes Animal housing must be empty of animals during application and re-entry of animals can be done 24h after the end of the application.

Example* for product with 2.5% iodine	Dilution of the product	Contact time
Bactericidal & Yeasticidal activity	*1% (10ml product, add water up to 1L)*	30 min
Virucidal activity	*1.4% (14ml product, add water up to 1L)*	30 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 2.5 to 3% it is not possible to give all product dilutions here

Do not mix with other chemicals.

Do not prepare more fluid than necessary.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 8.2

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall (material to be specified by the authorisation holder within the product information)and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product and eye/face protection (glove and coverall material to be specified by the authorisation holder within the product information).
- Only use one kind of Iodine-containing product per day.
- Due to potential concern for human health the professionals must not carry out animal house disinfection more than 3 times per months. These professionals should not use Iodine products for additional purposes.
- Due to potential concern for animal health, stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.
- Keep out of reach of children.
- The general public and animals should be kept away from treated areas until surfaces are dry.

Table 12: Use # 9.1 – *meta* SPC 9: PT4 - Concentrated– CIP disinfectants, Iodine

Product Type(s)	PT4
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Bacteria, yeasts
Field of use	CIP disinfection for milking equipment and CIP installations in Food industry
Application method(s)	CIP disinfection
Application rate(s) and frequency	Apply the product in the automatic system with a dilution of the product with water to an end concentration of 0.00125% available iodine. The product is used up to once per day in food industry and 2 times per day in milking parlours.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 9.1

Disinfection of milking machine or CIP installations in Food industry:

Clean first the CIP installation.
Apply the product in the automatic system with a dilution of the product (according to table below) with water.
Use at room temperature.
Respect a contact time according to the table below.
Rinse the installation with water.
The product is used up to 2 times per day

Example* for product with 0.5% iodine	Dilution of the product	Contact time
Bactericidal and Yeasticidal activity	*0.25% (2,5ml ml product, add water up to 1L)*	15 min. for bacteria & yeasts

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 0.5 to 1% it is not possible to give all product dilutions here. An example is given for products with 0.5% iodine

Do not mix with other chemicals.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 9.1

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves and protective coverall (at least type X, EN XXXXX) (glove and

coverall material to be specified by the authorisation holder within the product information) and eye/face protection.
- Keep out of reach of children.

Table 13. Use # 10.1 *meta* SPC 10: PT3 – Concentrated teat disinfectants, Post-milking, Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria, yeasts and viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By spraying with a manual sprayer or with an automatic sprayer on teats.
Application rate(s) and frequency	The product must be diluted before use in order to allow a final concentration of iodine of 0.3% Apply two times per day by using a manual sprayer and three times per day when using a robot (or automatic sprayer).
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 10.1

The product must be diluted before use in order to allow a final concentration of iodine of 0.3% . This product should be diluted to 11% (110ml product, add water up to 1L).

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The use of a dosing pump for filling the product into the application equipment is recommended.
Use gloves and eye protection during the dilution step. The diluted product can be kept and used during 1 week.

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

Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer.
The product should be used directly after milking 2 times per day by using a manual spayer and 3 times per day by using a robot (automatic sprayer). Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
Do not mix with other chemicals.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 10.1

- For mixing an loading of the product: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information) and eye/face protection.
- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 14. Use # 11.1 – PT3 – RTU teats disinfectants, Post-milking, Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria, yeasts
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying teats
Application rate(s) and frequency	The product is ready-to-use. Apply two times per day when using a manual sprayer and three times per day when using a dip cup or a robot (automatic sprayer).
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 11.1

Apply the product by dipping or by spraying:
-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use
-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
The product should be used immediately after each milking, two times per day when using a manual sprayer or three times per day when using a dip cup or a robot (automatic sprayer). Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes). Do not mix with other chemicals.

USE-SPECIFIC RISK MITIGATION MEASURES; USE # 11.1

- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

Table 15: Use # 12.1 – *meta* SPC12: PT3 – RTU Teat disinfectants, Post-milking, Iodine

Product Type(s)	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection ready to use
Target organism (including development stage)	Bacteria, yeasts, viruses
Field of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	The product is ready to use. Apply 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.
Category(ies) of user(s)	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

INSTRUCTIONS FOR USE; USE # 12.1

Apply the product by dipping or by spraying:
-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use
-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary; assume 5 mL solution per cow per treatment. The product must be brought to a temperature above 20°C before use. The use of a dosing pump for filling the product into the application equipment is recommended.
The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the animal standing at least 5 minutes).
Do not mix with other chemicals.

RISK MITIGATION MEASURES; USE # 12.1

- For manual spraying application: Wear chemical resistant gloves (material to be specified by the authorisation holder within the product information).
- For manual dipping application: no PPE is necessary for safe use.
- In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.
- Keep out of reach of children.

D. HAZARD AND PRECAUTIONARY STATEMENTS

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

Classification: metaSPC 1	
Hazard category	Eye Dam. 1, Aquatic Chronic 3, STOT RE 2
Hazard statement	H318 Causes serious eye damage H412 Harmful to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure.
Labelling	
Signal words	Danger
Hazard statements	H318 Causes serious eye damage H412 Harmful to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure.
Precautionary statements	P280 - Wear eye protection, protective clothing, protective gloves P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a doctor, a POISON CENTER P273 – Avoid release to the environment P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 2, metaSPC 4, metaSPC 5, metaSPC 11 and meta SPC 12	
Hazard category	Aquatic Chronic 3
Hazard statement	H412 Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H412 Harmful to aquatic life with long lasting effects
Precautionary statements	P273 – Avoid release to the environment P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 3	
Hazard category	Aquatic Chronic 3
Hazard statement	H412 Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H412 Harmful to aquatic life with long lasting effects
Precautionary statements	P273 – Avoid release to the environment P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 6	
Hazard category	Aquatic Chronic 3, STOT RE 2
Hazard statement	H412 Harmful to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure
Labelling	
Signal words	Warning
Hazard statements	H412 Harmful to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure
Precautionary statements	P260 – Do not breathe spray. P273 – Avoid release to the environment P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 7	
Hazard category	Met. Corr. 1, Eye Dam. 1, Aquatic Chronic 2, STOT RE 2
Hazard statement	H290 May be corrosive to metals H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure.
Labelling	
Signal words	Danger
Hazard statements	H290 May be corrosive to metals H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure.

Precautionary statements	P280 - Wear eye protection, protective clothing, protective gloves P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a doctor, a POISON CENTER P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 8	
Hazard category	Met. Corr. 1, Skin irrit. 2, Eye Dam. 1, Aquatic Chronic 2, STOT RE 2
Hazard statement	H290 May be corrosive to metals H315 Causes skin irritation. H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure
Labelling	
Signal words	Danger
Hazard statements	H290 May be corrosive to metals H315 Causes skin irritation H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure
Precautionary statements	P280 - Wear protective gloves/protective clothing/eye protection/face protection P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician P303+P361+P353+P310: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 9	
Hazard category	Met. Corr. 1, Skin Corr. 1, Eye Dam. 1, Aquatic Chronic 3,
Hazard statement	H290 May be corrosive to metals H314 Causes severe skin burns and eye damage H318 Causes serious eye damage H412 Harmful to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Hazard statements	H290 May be corrosive to metals H314 Causes severe skin burns and eye damage H412 Harmful to aquatic life with long lasting effects
Precautionary statements	P280 - Wear protective gloves/protective clothing/eye protection/face protection P305+P351+P338+P310: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician P303+P361+P353+P310: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician P273 – Avoid release to the environment P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

Classification: metaSPC 10	
Hazard category	Eye Dam. 1, Aquatic Chronic 2, STOT RE 2
Hazard statement	H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure
Labelling	
Signal words	Danger
Hazard statements	H318 Causes serious eye damage H411 Toxic to aquatic life with long lasting effects H373 May cause damage to thyroid through prolonged or repeated exposure, oral exposure

Precautionary statements	P280 - Wear eye protection, protective clothing, protective gloves P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P310 - Immediately call a doctor, a POISON CENTER P273 – Avoid release to the environment P391 – Collect spillage P501 – Dispose of contents/containers to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation
Note	

E. PACKAGING OF THE BIOCIDAL PRODUCT

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottles, jerrycans or containers	1, 5, 10, 20, 25, 30, 60, 200, 600, 1000 L	HDPE (High Density polyethylene)	Cap in HDPE (High Density polyethylene)	Professionals	Yes

Summary of the physical, chemical and technical properties

Identity and physical and chemical properties.

The biocidal product family consists of 12 meta SPCs, including products based on iodophore 1 (surfactant complex) and 2 (PVP-iodine). In the confidential annex (separate document), the composition of the family, the meta SPCs and the representative products are described. The family consists of ready to use products, but also products to be applied in dilutions.

Products within the family are all dark brown liquids with a pungent odour. The pH range of the products throughout the family is wide, at approximately pH 1 for the CIP products to 6 for the skin disinfectants. The products within the family are water based and therefore generally have a density of approximately 1.

Stability

Stability data resulted in the following conclusions:

Meta SPC	Formulation type	Shelf-life (years) in HDPE at 25°C	Efficacy data submitted to support shelf-life	Maximum storage temperature (°C)	Minimum storage temperature (°C)
1	SL	2	Not necessary	40	'protect from frost' recommendation required
2	AL	2	Yes	40	'protect from frost' recommendation required
3	AL	2	Yes	40	'protect from frost' recommendation required
4	AL	2	Not necessary	40	'protect from frost' recommendation required
5	AL	1.5 (18 months)	Not necessary	40	'protect from frost' recommendation required
6	AL	2	Not necessary	40	'protect from frost' recommendation required
7	SL	2	Not necessary	40	'protect from frost' recommendation required
8	SL	2	Not necessary	40	'protect from frost' recommendation required
9	SL	2	Yes	40	'protect from frost' recommendation required

10	SL	2	Not necessary	40	'protect from frost' recommendation required
11	AL	2	Yes	40	'protect from frost' recommendation required
12	AL	2	Yes	40	'protect from frost' recommendation required

Other stability data

Dilutions of products can be stored for 1 week in which they remain stable, based on efficacy data.

Storage related breakdown products

When the active substance degrades by more than 10%, the influence of such degradation with regard to hazard should be addressed. Considering iodine is a non-specific oxidiser, it is considered acceptable that the breakdown products are not identified. The breakdown products should be iodide ions and oxidised material. What compounds are formed is difficult to identify. It is not expected any specific hazardous compounds are formed in the process.

Technical properties

Foam persistence and dilution stability

Foaming and dilution stability were investigated for the appropriate meta SPCs 1 and 7-10.

Particle size (MMAD)

The particle size of the sprays was not determined considering:

1. The droplet is not used in the efficacy or toxicological assessment
2. Packs are not equipped or sold together with spray attachments

Surface tension and viscosity

Data on surface tension is available for all meta SPCs. Viscosity data is only provided for products that are thickened. The non-thickened products are expected to have a viscosity similar to that of water.

Physical and chemical hazards

With respect to classification and labelling, the iodine products are generally not classified with regard to physical and chemical hazards; they are not flammable, explosive or oxidising in the sense of Regulation (EC) 1272/2008.

However, data was provided showing that products within meta SPCs 7, 8 and 9 are metal corrosive (H290).

Analytical methods

A thiosulfate titration method was provided, sufficiently validated to allow the accurate determination of the iodine content in all (potential) products in the family.

Methods for relevant impurities and substances of concern are not deemed required.

The residue analytical methods were addressed at substance evaluation level and were not reconsidered.

Summary of the Human Health Risk Assessment

Endpoint	**Brief description**
Skin corrosion and irritation	MetaSPC 1, 2, 3, 4, 5, 6, 7, 10, 11 and 12 are not classified regarding skin corrosion/irritation. MetaSPC 8 is classified with H315 and 9 is classified as H314.
Eye irritation	Products of metaSPC 1, metaSPC 7, 8 and metaSPC 10 are damaging for eyes according to the CLP classification. Products of metaSPC 9 are corrosive for eyes according to the CLP classification. Products of metaSPC 2, 3, 4, 5, 6, 11 and 12 are not irritant and not corrosive for eyes.
Skin sensitisation	Products of the BPF are not considered as skin sensitizing according to the CLP regulation.
Sensitization	Products of the BPF are not considered as sensitizing according to the CLP regulation.
Respiratory sensitization (ADS)	Products of the BPF are not considered as respiratory sensitizing according to the CLP regulation.
Acute toxicity by oral route	Products of the BPF are not considered as acute toxic by oral route according to the CLP regulation.
Acute toxicity by inhalation	Products of the BPF are not considered as acute toxic by inhalation route according to the CLP regulation.
Dermal absorption	As member of IRG group, we have access to the study on percutaneous absorption performed on Iodine by IRG (OCDE 428, section A6.2/10 of the IRG file). Study was performed on teat disinfectant ready-to-use products containing 0.26% to 0.66% of total iodine and shows a dermal penetration of 11.3% to 12.0%. As the concentration of iodine in the teat disinfectant products (ready-to-use) of metaSPC 1, 2, 3, 4, 5, 6, 10, 11 and 12 is comparable (0.3% to 1%) to the content of iodine used in the OCDE testing, the dermal absorption of 12% is considered relevant for ready-to-use teat and skin disinfectants. Products of meta SPC 7, 8 and 9 are used in low concentrations also, and the data of 12% is also used.
Other effects	Not applicable
Available toxicological data relating to non active substance(s)	• Acohols, C12-15, ethoxylated:practically non-toxic by inhalation route and has a LD50 >2000 mg/kg by dermal route • Phosphoric acid: SCOEL values available, no skin notation. 8-h TWA = 0.1 mg/m3 .
Available toxicological data relating to a mixture	Not applicable
Other relevant information	Based on the classification rules and the concentration of the active substance, metaSPC 1, 3, 6, 7, 8 and 10 need to be classified with H373: May cause damage to organs thyroid through prolonged or repeated exposure, oral route.

Reference values

	Study	NOAEL/ LOAEL	Overall assessment factor	Value
Iodine				
Upper Intake Level (UIL)	Human data (CAR value)	UIL	-	600 µg/day (0.01 mg/kg bw/d)
ADI	Not derived in the CAR and not relevant for HHRA. Instead of an ADI, a Recommended daily intake of 150-200 µg/day is given in the CAR.			
AEC = OEL (Occupational exposure limit)	Human data (CAR value)		-	0.1 ppm / 1 mg/m3
Phosphoric acid (SoC)				
8-hour TWA	SCOEL report			0.2 ppm for vapour/ 1 mg/m3
15-min STEL	SCOEL report			0.5 ppm for vapour/ 2 mg/m3
	Note: a 'skin'notation was not considered necessary as skin absorption would not contribute significantly to the normal body load of phosphate			

Risk characterisation

Conclusion of risk characterisation for industrial user

Risk from the industrial use of products included in metaSPC7-9 are acceptable when taking the following RMM:

metaSPC7 PT4:

- During pouring of the concentrated product: chemical resistant gloves and eye/face protection.
- During pumping of the product: chemical resistant gloves and eye/face protection.
- During spraying of the product: chemical resistant gloves, coated coverall

metaSPC8 PT4:

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and coated coverall.

metaSPC9 PT4:

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.

Risk from the professional use of products included in metaSPC1-9 are acceptable when taking the following RMM:

metaSPC1 and 10 PT3:
- For mixing an loading of the product: Wear chemical resistant gloves and eye/face protection.
- For manual spraying application: Wear chemical resistant gloves.

metaSPC2, 5, 11 en 12, PT3:
- For manual spraying application: Wear chemical resistant gloves
- For manual dipping application: no PPE is necessary for safe use.

metaSPC3 PT3:
- For manual spraying application on cows and sows: Wear chemical resistant gloves.

metaSPC4 PT3:
Teat disinfectant
- For manual spraying application: Wear chemical resistant gloves
- For manual dipping application: no PPE is necessary for safe use.

Skin disinfectant
- For manual spraying application on cows and sows: no PPE is necessary for safe use.

metaSPC6, PT3:
- For manual spraying application on cows and sows: Wear chemical resistant gloves.

metaSPC7 PT3:
- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and an impermeable coverall.

metaSPC8 PT3:
- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.
- During spraying of the product: Wear chemical gloves and impermeable coverall.

metaSPC9 PT3:
- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall and eye/face protection.

Conclusion of risk characterisation for non-professional user

Risk for the general public (secondary exposure via oral route) is assessed to be safe as described in the IRG study "Discussion paper – iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety".

Summary of the Environmental Risk Assessment

Summary table: environment scenarios			
Use		**Description of scenario including environmental compartments**	**Conclusion**
#1.1	Post-milking teat disinfectant (PT03)	Active substance is released to the: • manure and subsequent to soils when manure is applied as a fertiliser. Groundwater and surface water are secondary exposed to leaching and run-off; • the sewer and subsequent to the sewage treatment plant and surface water including sediment. Soils and groundwater will be exposed due to the distribution of sewage sludge.	Acceptable, but a precautionary measure is added regarding emission to individual wastewater treatment plants
#2.1	Post-milking teat disinfection (PT03)		
#3.1	Animal skin disinfection only for use on intact skin (PT03)		
#4.1	Post-milking teat disinfectant (PT03)		
#4.2	Animal skin disinfection, only for use on intact skin (PT03)		
#5.1	Post-milking teat disinfection (PT03)		
#6.1	Animal skin disinfection, only for use on intact skin (PT03)		
#7.1	Surface disinfection – professional kitchens and food industry (PT04)	Active substance is released to the sewer and subsequent to the sewage treatment plant and surface water including sediment. Soils and groundwater will be exposed due to the distribution of sewage sludge.	Acceptable
#7.2	Surface disinfection - veterinary field (PT03)	See 1.1	Acceptable, but a precautionary measure is added regarding emission to individual wastewater treatment plants
#8.1	Surface disinfection – food industry (PT04)	See 7.1	Acceptable
#8.2	Surface disinfection - veterinary field (PT03)	See 1.1	Acceptable, but a precautionary measure is added regarding emission to individual wastewater treatment plants
#9.1	CIP disinfection (PT04)	See 7.1. As no scenarios are available for CIP-disinfection using iodine, emission was calculated based on information submitted by the applicant.	Acceptable
#10.1	Post-milking teat disinfectant (PT03)	See 1.1	Acceptable, but a precautionary measure is added regarding emission to individual wastewater
#11.1	Post-milking teat disinfectant (PT03)		

# 12.1	Post-milking teat disinfectant (PT03)		treatment plants

- Although PNEC may be exceeded in soils and water including sediment, and the concentration in groundwater is above 0.1 µg/L, no unacceptable risks are expected as: iodine will exist in the least toxic species in soils for which no exceeding of the PNEC was calculated;
- all PECs are within the natural background concentration for each compartment exposed.

Release to on-site individual wastewater treatment plants may result in malfunction of the systems when released to the sewer (PT03 only). Therefore, a precautionary measure was added stating that residues must be released to the manure deposit or the sewer where allowed.

2.2 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

Administrative information

A. TRADE NAME OF THE PRODUCT/TRADE NAME(S) OF THE PRODUCTS OF THE FAMILY[1]

Trade name[2]	**Country (if relevant)**
<u>metaSPC 1.1:</u> Kenodin SD 400 IodoSD 400 Velvet Concentrate Wynnsan Iodine 3 - 1 conc Iodin Teat Spray 400 <u>metaSPC 2.1:</u> Kenodin IodoDip 3000 Bio Tec Jodip 3000 Recoïode Stalosan Io Dip Stalosan Super Dip Velvet High Visco Bühning Joddip 3000 Wynnsan trikill RTU Wynnsan Iodine RTU teat dip Wynnsan Iodine dip RTU Iocid Iodip+ Wynngold Iodine Dip Pezerk iv plus Iod protect 3000 Film Seivit® Iode 3000 Kenostart GAHERYOD Kenodin 3000 Iodin Teat Dip 3000 Iod 3000 dip Iodoschutz dip Ioschutz dip Iodocoop dip Iodotech dip Iodactiv' dip Iododip MIROX Dip Jod	Union Authorisation

1 Please delete as appropriate.

2 In case the product would have more than one name, all names can be provided in this field, if the other elements of the SPC are identical. Otherwise additional SPCs would have to be provided (one SPC per name).

Trade name[2]	**Country (if relevant)**
HCP Iodine Dip Agib Jodium Dip Jod 3000 Iod dip Iode 3000 Iodoschutz Coopjod Coopiode Coopiode épais Semex jod Iodotech Iododip green Iodip bio Iododip bio Iodactive épais Iodactiv Iodoactiv' Bayley's Premier Iodine Teat Dip Pearce Premier Iodine Teat Dip Diamond 1:3 Concentrate Iodine Post Dip Spray JODOCARE KENOSTART DYP STREPTOFIT Iodall Film <u>metaSPC 2.2:</u> Kenodin Film IodoFilm Wynnsan Iofilm teat dip Kenodin Film Extra Wynngold Film Wynnsan trikill film teat dip Kenodin Film Soft Iocid Film TOP Film Seivit® Iode Gel IOD protect 3000 Film Iodin Film Teat Dip 3000 Iodin Barrier Teat Dip 3000 Iodin Film Teat Dip Iodin Barrier Teat Dip Iod 3000 film Iodoschutz film Ioschutz film Iodocoop film Iodotech film Iodactiv' film Iodofilm	

Trade name[2]	Country (if relevant)
HCP Iodine Film Iod 3000 film Coopjod film Coopiode film Iodocoop film Semex jod film Iodofilm Iodofilm bio Iofilm bio Iodactive film Iodactiv film Iodactiv' film SCUDO 3000 metaSPC 3.1: Animal skin disinfectant Dermades 3000 Iodin Skin Disinfectant metaSPC 3.2: Dermades Animal skin disinfectant 1% Dermades Strong Iodin Skin Disinfectant Strong metaSPC 4.1: Kenodin SD IodoSD 3000 Bio Tec Jodspray 3000 Q Farm Iodine Des ANRO – Euterpflege Dip Stalosan Io Spray Stalosan Super spray Wynnsan trikill spray Wynnsan Iodine spray RTU IDip+ Bühning Jodspray 3000 Velvet RTU Wynngold Iodine Dip and spray Pezerk IL Iod protect 3000 Sprüh Seivit® Iode Spray IOD protect 3000 Sprüh Kenodin SprayFilm Iodo SP Kenostart SD GAHERYOD SPRAY Iodin Teat & Skin 3000 Iod 3000 sprüh Iodoschutz sprüh	

Trade name[2]	Country (if relevant)
Ioschutz sprüh Iodocoop sprüh Iodotech sprüh Iodactiv' sprüh Iodosprüh MIROX Spray Jod HCP Iodine SD Agib Jodium Spray Jod 3000 spray Iod sprüh Coopjod Coopiode spray Iodocoop spray Semex jod spray Iododip spray Iododip spray green Iodospray Bio Iospray bio Iodactive spray Iodactiv spray Iodactiv' spray Ark Iodine S+D Agrihealth Iodine SD AGRO LOGIC JODOCARE SPRAY IODACTIVE metaSPC 5.1: Iodo PVP Iodin Teat Dip 3000 PVP metaSPC 5.2: Iodo SD PVP Iodin Teat Spray & Dip 3000 PVP metaSPC 6.1: Dermades PVP Iodin Skin Disinfectant PVP Wynngold 10% Iodine Solution metaSPC 7.1: Dodin 20 Iodo 20 Bio Tec Joddesinfektion Dufa dine 1,8% Alfasan super disinfectant Iodes Streptoclean Iodin Surface Disinfectant 1,8% IODINE	

Trade name[2]	Country (if relevant)
metaSPC 8.1: Iocid 30 Iodo 30 Dufa dine Iodin Surface Disinfectant 2,8% metaSPC 9.1: Iodo CIP Iocip Bio Tec Jodreiniger JODOPHOS SUPER 4001 Bühning Jodreiniger Wynnsan Ice bank Tank Cleaner Bulk Tank Sanitizer Iodin CIP Disinfectant metaSPC 10.1: Kenodin SD 900 IodoSD 900 IDip+ concentrate Jodkonzentrat 1:9 Bühning Jodkonzentrat 1:9 Wynnsan Iodine Conc dip 9-1 Kenodin 900 Dufa Dip Kenostart 900 Iodin Teat Spray 900 HCP Iodine Concentrate Maxi Subliem CP Subliem Koncentrat Plus metaSPC 11.1: Kenodin 2500 Iodin Teat Dip 2500 Jod 2500 metaSPC 12.1: Kenodin 5000 IodoDip 5000 JOD 5000 Bio Tec Jodip 5000 Bühning Jodfilmdip-Super Iocid 5000 Iod protect 5000 Film IOD protect 5000 Film Iocid Iodip+ Protetos cua Iodin Teat Dip 5000	

Trade name[2]	Country (if relevant)
metaSPC 12.2: Kenodin SD 5000 IodoSD 5000 IODOSPRAY 5000 Bio Tec Jodspray 5000 IDip+ 5000 Bühning Jodspray 5000 Iod protect 5000 Sprüh Kenodin Film Spray IOD protect 5000 Sprüh Iodin Spray & Dip 5000	

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	Name	CID LINES NV
	Address	Waterpoortstraat 2, 8900 Ieper, Belgium
Telephone:	0032 57 21 78 77	
Fax:	0032 57 21 78 79	
E-mail address:	regulatory.affairs@cidlines.com	
Pre-submission phase started on:	27 March 2015	
Pre-submission phase concluded on:	3 June 2015	
Case number in R4BP3:		

C. APPLICANT (IF DIFFERENT FROM AUTHORISATION HOLDER)

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

D. PERSON AUTHORISED FOR COMMUNICATION ON BEHALF OF THE APPLICANT

Name:	[redacted]
Function:	Regulatory Affairs Officer
Address:	Waterpoortstraat 2
City:	Ieper
Postal Code:	8900
Country:	Belgium
Telephone:	0032 57 21 78 77
Fax:	0032 57 21 78 79
E-mail address:	[redacted]

Name:	[redacted]
Function:	Regulatory Affairs Officer
Address:	Waterpoortstraat 2
City:	Ieper
Postal Code:	8900
Country:	Belgium
Telephone:	0032 57 21 78 77
Fax:	0032 57 21 78 79
E-mail address:	[redacted]

Name:	[redacted]
Function:	Regulatory Affairs Manager
Address:	Waterpoortstraat 2
City:	Ieper
Postal Code:	8900
Country:	Belgium
Telephone:	0032 57 21 78 77
Fax:	0032 57 21 78 79
E-mail address:	[redacted]

E. MANUFACTURER(S) OF THE PRODUCTS OF THE FAMILY

Product manufacturers

Name of manufacturer	CID LINES NV
Address of manufacturer	Waterpoortstraat 2, 8900 Ieper, Belgium
Location of manufacturing sites	Waterpoortstraat 2, 8900 Ieper, Belgium

Active substance manufacturers

Active substance	Iodine

Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan
Location of manufacturing sites	Shirasato Plant (3695 Kitaimaizumi, Oamishirasato City 299-3201 Chiba Japan)

Active substance	PVP-Iodine
Name of manufacturer	ISP Chemicals LLC, Afiliate of Ashland Inc
Address of manufacturer	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
Location of manufacturing sites	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

Active substance	PVP-Iodine
Name of manufacturer	Pantheon FZE (DMCC Branch)
Address of manufacturer	403, Reef Tower, Jumeira Lake Tower Shaikh Zayed Road – Dubai Émirats arabes unis
Location of manufacturing sites	Cosayach Nitratos S.A. Oficina Cala Cala S/N – Pozo almonte Iquique Chili

F. CANDIDATE(S) FOR SUBSTITUTION

CID LINES NV Iodine based products doesn’t contain an active substance candidate for substitution.

Product (family) composition and formulation

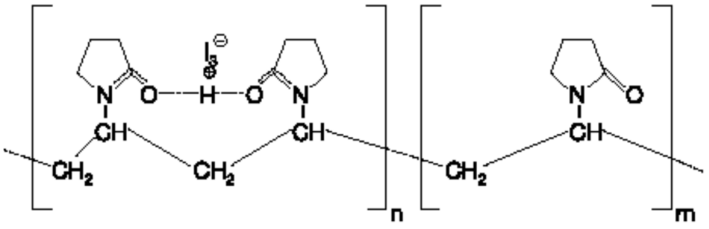
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☐
No x

A. IDENTITY OF THE ACTIVE SUBSTANCES

Main constituent(s): Iodine	
ISO name	-
IUPAC or EC name	Iodine
EC number	231-442-4
CAS number	7553-56-2
Index number in Annex VI of CLP	053-001-00-3
Minimum purity / content	>99%
Structural formula	I-I

Main constituent(s): PVP-Iodine	
ISO name	-
IUPAC or EC name	Polyvinylpyrrolidone iodine
EC number	-
CAS number	25655-41-8
Index number in Annex VI of CLP	PVP-iodine releases the active substance iodine for which the index number in annex VI of CLP is 053-001-00-3.
Minimum purity / content	>99% (referring to iodine) PVP-iodine, pharmaceutical grade, contains 9 – 12% iodine and up to 6% iodide.
Structural formula	

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine / PVP - Iodine	Iodine	Active substance	7553-56-2	231-442-4	0	3.0
	PVP-Iodine	Active substance	25655-41-8	-	0	10.0 (1.2% Iodine)
Alcohols, C12-15, ethoxylated	Alcohols, C12-15, ethoxylated	Non-active substance	68131-39-5	500-195-7	0	21.0
Alcohol C9-11 + 6 EO	Alcohol C9-11 + 6 EO	Non-active substance	68439-46-3	-	0	12.5
Phosphoric acid	Phosphoric acid	Non-active substance	7664-38-2	231-633-2	0	30.0

According to the pharmacopoeia, PVP-iodine contains 9 – 12% iodine by mass and up to 6% iodide. See also section 3.4 of the confidential annex for more information on total iodine calculations.
Total iodine is calculated based on the iodine from all iodine sources within the product. See confidential attachment for more information (section 3.4).

C. INFORMATION ON TECHNICAL EQUIVALENCE

All sources, four for iodine and two for PVP-iodine, were considered in the CAR (confidential annex, doc IIIA1) and are considered reference sources. An assessment of technical equivalence is not necessary for these sources.

D. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

Please refer to section B for information on the active substance content and the content of substances of concern (phoshphoric acid and alcohols, C12-15, ethoxylated). Please see the confidential annex for further details regarding SoCs and the risk assessment and the full composition of the family and its formulations.

E. TYPE OF FORMULATION

SL: Soluble liquid (metaSPC 1, metaSPC 7, metaSPC 8, metaSPC 9 and metaSPC 10) AL: Other liquids to be appied undiluted (metaSPC 2, metaSPC 3, metaSPC 4, metaSPC 5, metaSPC 6, metaSPC 11 and metaSPC 12)

Intended use(s) as applied for by the applicant

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters. The uses authorised are summarised in 2.2.1 C.

Table 1: Use # 1.1 – metaSPC 1: PT3 – Concentrated Teat disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfectant, concentrated
Target organism (including development stage)	Bacteria, yeast and viruses
Field of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By manual or automatic spraying on teats
Application rate(s) and frequency	The product has to be diluted: mixed with of clean potable water to allow a final concentration of 0,3% (w/w) available iodine. The ready to use solution can be kept and used during 1 week, but do not prepare more fluid than necessary. Assume 5 mL per cow per treatment . Apply the ready to use solution immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarters of its length.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 2: Use # 2.1 – metaSPC 2: PT3 – RTU Teat disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection ready to use
Target organism (including development stage)	Bacteria, yeast, viruses

Field of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying on teats
Application rate(s) and frequency	Apply the product immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid that necessary. Assume 5 mL per cow per treatment.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 3: Use # 3.1 – metaSPC 3: PT3 – RTU Skin disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Animal skin disinfection, only for use on intact skin Ready to use
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Skin disinfection, only for use on intact skin of: - Dairy and beef cattle: on the udder before calving - Sows: before farrowing
Application method(s)	By spraying
Application rate(s) and frequency	Apply by spraying on the animals' skin (intact) for a topical disinfection of: - dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application) - sows before farrowing: 15 to 20 mL per animal
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

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

Table 4: Use # 3.2 – metaSPC 3: PT3 – RTU Hoof* disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Animal hoof disinfection Ready to use
Target organism (including development stage)	Bacteria
Field of use	Veterinary field: hoof disinfection
Application method(s)	By spraying
Application rate(s) and frequency	Apply by spraying on animals' hooves to avoid cross contamination.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

* During the evaluation the applicant withdraw the use as hoof disinfectant and added the following uses as skin disinfectants:

Cattle, sheep, goats and pigs: on coronary band and interdigital skin of hooves when a new animal is joining the herd

Horses: on coronary band and frog when a new animal is joining the herd.

This was not accepted in this late state of the evaluation

Table 5: Use # 4.1 – metaSPC 4: PT3 – RTU Teat disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfectant
Target organism (including development stage)	Bacteria, yeast and viruses
Field of use	Indoor

	Ready to use teat disinfectant to be used post-milking on milk producing animals.
Application method(s)	Application on teats: by dipping or spraying
Application rate(s) and frequency	*Application as a teat dip/spray:* Apply the product immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid that necessary. Assume 5 mL per cow per treatment.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 6: Use # 4.2 – metaSPC 4: PT3 – RTU Skin disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Animal skin disinfection, only for use on intact skin Ready to use
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Ready to use skin disinfectant, only for use on intact skin of: - dairy and beef cattle: on the udder before calving - sows before farrowing
Application method(s)	Application on animal skin: by spraying
Application rate(s) and frequency	Apply by spraying on the animals' skin (intact) for a topical disinfection: - dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application) - sows before farrowing: 15 to 20 mL per animal
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of	Yes

food/feedingstuff (yes/no)	

Table 7: Use # 4.3 – metaSPC 4: PT3 – RTU Hoof* disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Disinfection of hooves
Target organism (including development stage)	Bacteria
Field of use	Veterinary field: Ready to use hoof disinfectant
Application method(s)	Application on animal hooves: by spraying
Application rate(s) and frequency	*Application on animals' hooves:* Apply by spraying on animals' hooves to avoid cross contamination.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

* During the evaluation the applicant withdraw the use as hoof disinfectant and added the following uses as skin disinfectants:
Cattle, sheep, goats and pigs: on coronary band and interdigital skin of hooves when a new animal is joining the herd
Horses: on coronary band and frog when a new animal is joining the herd.
This was not accepted in this late state of the evaluation. Moreover, the treatment of the coronary band can be seen as part of the treatement of hoofs and is therefore not a separate use as skin disinfectant.

Table 8: Use # 5.1 – metaSPC 5: PT3 – RTU Teat disinfectants PVP-Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection ready to use
Target organism (including development stage)	Bacteria, yeast, viruses
Field of use	Indoor Post-milking disinfection on teats of milk producing animals

Application method(s)	By spraying or dipping on teats
Application rate(s) and frequency	Apply the product immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid that necessary. Assume 5 mL per cow per treatment.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 9: Use # 6.1 – metaSPC 6: PT3 – RTU Skin disinfectants PVP-Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Animal skin disinfection, only for use on intact skin Ready to use
Target organism (including development stage)	Bacteria, yeast
Field of use	Indoor Ready to use skin disinfectant, Only for use on intact skin of: - dairy and beef cattle: on the udder before calving - sows before farrowing
Application method(s)	Application on animal skin: by spraying
Application rate(s) and frequency	Apply by spraying on the animals' skin (intact) for a topical disinfection: - dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application) - sows before farrowing: 15 to 20 mL per animal
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 10: Use # 6.2 – metaSPC 6: PT3 – RTU Hoof* disinfectants PVP-Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Animal hoof disinfection ready to use
Target organism (including development stage)	Bacteria
Field of use	Veterinary field: Ready to use hoof disinfectant
Application method(s)	By spraying
Application rate(s) and frequency	Apply by spraying on animals' hooves to avoid cross contamination.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

* During the evaluation the applicant withdraw the use as hoof disinfectant and added the following uses as skin disinfectants:

Cattle, sheep, goats and pigs: on coronary band and interdigital skin of hooves when a new animal is joining the herd

Horses: on coronary band and frog when a new animal is joining the herd.

This was not accepted in this late state of the evaluation.

Table 11: Use # 7.1 – metaSPC 7: PT4– Surface disinfectants Iodine

Product Type	PT4
Where relevant, an exact description of the authorised use	Surface disinfection
Target organism (including development stage)	Bacteria and yeast
Field of use	Surface disinfection in food industry
Application method(s)	By spraying with a back pulverisator or an automatic sprayer
Application rate(s) and frequency	First clean the surfaces thoroughly. Dilute the product at the required concentration. Bactericidal activity: 0.015% iodine Yeasticidal activity: 0.0125% iodine Disinfect by spraying respecting a contact time of 15

	minutes. Rinse the surfaces after the contact time with clean water. Do not prepare more fluid than necessary. Make 0.04L solution for every square meter that has to be disinfected. In the food industry, working areas can be disinfected everyday while other areas are disinfected only once a week.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 12: Use # 7.2 – metaSPC 7: PT3 – Surface disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Surface disinfection
Target organism (including development stage)	Bacteria, yeast and viruses
Field of use	Surface disinfection in veterinary field
Application method(s)	By spraying with a back pulverisator or an automatic sprayer
Application rate(s) and frequency	First clean the surfaces thoroughly. Dilute the product at the required concentration. Bactericidal activity: 0.025% in-use iodine Yeasticidal activity: 0.025% in-use iodine Virucidal activity: 0.035% in-use iodine Disinfect by spraying respecting a contact time of 30 minutes. Rinse the surfaces after the contact time with clean water. Do not prepare more fluid than necessary. Make 0.04L solution for every square meter that has to be disinfected.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 13: Use # 8.1 – metaSPC 8: PT4– Surface disinfectants Iodine

Product Type	PT4
Where relevant, an exact description of the authorised use	Surface disinfection
Target organism (including development stage)	Bacteria and yeast
Field of use	Surface disinfection in food industry
Application method(s)	By spraying with a back pulverisator or an automatic sprayer
Application rate(s) and frequency	First clean the surfaces thoroughly. Dilute the product at the required concentration. Bactericidal activity: 0.015% iodine Yeasticidal activity: 0.0125% iodine Disinfect by spraying respecting a contact time of 15 minutes. Rinse the surfaces after the contact time with clean water. Do not prepare more fluid than necessary. Make 0.04L solution for every square meter that has to be disinfected. In the food industry, working areas can be disinfected everyday while other areas are disinfected only once a week.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 14: Use # 8.2 – metaSPC 8: PT3 – Surface disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Surface disinfection
Target organism (including development stage)	Bacteria, yeast, viruses
Field of use	Surface disinfection in veterinary field
Application method(s)	By spraying with a back pulverisator or an automatic sprayer
Application rate(s) and frequency	First clean the surfaces thoroughly. Dilute the product at the required concentration.

	Bactericidal activity: 0.025% in-use iodine Yeasticidal activity: 0.025% in-use iodine Virucidal activity: 0.035% in-use iodine Disinfect by spraying respecting a contact time of 30 minutes. Rinse the surfaces after the contact time with clean water. Do not prepare more fluid than necessary. Make 0.04L solution for every square meter that has to be disinfected.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	Yes
Potential for contamination of food/feedingstuff (yes/no)	Yes

Table 15: Use # 9.1 – metaSPC 9: PT4– CIP disinfectants Iodine

Product Type	PT4
Where relevant, an exact description of the authorised use	Disinfection of CIP systems.
Target organism (including development stage)	Bacteria, yeasts
Field of use	CIP disinfection for milking equipment and CIP installations in Food industry
Application method(s)	CIP disinfection
Application rate(s) and frequency	CIP installations: disinfect with a dilution of the product with water. Clean first the CIP installation. Apply the product in the automatic system with a dilution of the product (according to table below) with water. Respect a contact time according to the table below. **Formula** | **Dilution** | **Contact time** Formula with 0.5% iodine | 0.25% | 5 min Formula with 1% iodine | 0.125% | 5 min Rinse the installation with water. The product is used up to once per day in food industry and 2 times per day in milking parlours.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)

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

Table 16. Use # 10.1 –metaSPC 10: PT3 – Concentrated teats disinfectants Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfectant, concentrated
Target organism(s) (including development stage)	Bacteria, yeast and viruses
Field(s) of use	Indoor Post-milking teat disinfection of milk producing animals
Application method(s)	By spraying with a manual sprayer or with an automatic sprayer on teats.
Application rate(s) and frequency	The product has to be diluted: mixed with clean potable water to allow a final concentration of 0.3% (w/w) available iodine. The ready to use solution can be kept and used during 1 week, but do not prepare more fluid than necessary. Assume 5 mL per cow per treatment . Apply the ready to use solution immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarters of its length.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	yes
Potential for contamination of food/feedingstuff (yes/no)	yes

Table 17. Use # 11.1 – meta SPC 11: PT3 – RTU teats disinfectants - Iodine

Product Type	PT3
Where relevant, an exact description of the authorised use	Post-milking teat disinfection ready to use
Target organism(s) (including development stage)	Bacteria, yeast
Field(s) of use	Indoor

	Post-milking teat disinfection of milk producing animals
Application method(s)	By dipping or spraying teats
Application rate(s) and frequency	Apply the product immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarters of its length. Fill the dipping cup or spraying flacon with the desired amount of product, but do not use more fluid that necessary. Assume 5 mL per cow per treatment.
Category(ies) of users	Professional use
Pack sizes and packaging material	1L, 5L, 10L, 20L, 25L, 30L, 60L, 200L, 600L, 1000L HDPE (High Density Polyethylene)
Potential for release into the environment (yes/no)	yes
Potential for contamination of food/feedingstuff (yes/no)	yes

Directions for use

A. INSTRUCTIONS FOR USE

Use # 1.1 – *meta* SPC 1: PT3 – Concentrated Teat disinfectants Iodine

The product must be diluted before use in order to allow a final concentration of iodine of 0.3%. This product should be diluted to 20% (200ml product, add water up to 1L). Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. Use gloves and eye protection during the dilution step. The ready to use solution can be kept and used during 1 week. Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer. The product should be used directly after milking 2 to 3 times per day by using a manual or automatic sprayer. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats, the animals should be kept standing for at least 5 minutes. For professional use only. Do not mix with other chemicals. Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 2.1 – *meta* SPC 2: PT3 – RTU Teat disinfectants Iodine

Apply the product by dipping or by spraying: *-By dipping:* Apply the product with a dip cup. Wash the dip cup with water after use *-By spraying:* Apply the product with a manual sprayer or with an automatic sprayer. Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats, the animals should be kept standing for at least 5 minutes. For professional use only. Do not mix with other chemicals. Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 3.1 – *meta* SPC 3: PT3 – RTU Skin disinfectants Iodine

For disinfection of the skin, :

Apply by spraying on the animals' skin (intact) for a topical disinfection:

- - dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. The animals should be kept standing on a clean floor for at least 5 minutes
- - sows on the udder before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once everyday during 4 days after farrowing. The animals should be kept standing on a clean floor for at least 5 minutes to let the product dry.

Only for use on intact skin.

For professional use only. Do not mix with other chemicals.

Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 3.2 – metaSPC 1.3: PT3 – RTU Hoof disinfectants Iodine*

For disinfection of the hooves:

- Dairy and beef cattle: Apply the product on the hooves (1 to 3 spray per hoof) of a new cow before including a new animal in the herd.

Let the product dry on the hooves. The animals should be kept standing on a clean floor for at least 5 minutes, to get adequate disinfection.

For professional use only. Do not mix with other chemicals.

Use Restrictions:	Not applicable

* originally applied for by the applicant but not authorised.

Use # 4.1 – *meta* SPC 4: PT3 – RTU Teat disinfectants Iodine

For disinfection of the teats:

- By dipping: Apply the product on the teats with a dip cup. Wash the dip cup with water after use.
- By spraying: Apply the product on the teats with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The product should be used directly after milking by using a dipping cup or a manual or automatic sprayer. Ensure that the teat is completely covered to three quarters of its length.

The product is applied after milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot.

Let the product dry on the teats. The animals should be kept standing for at least 5 minutes.

For professional use only. Do not mix with other chemicals.

Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 4.2 – *meta* SPC 4: PT3 – RTU Skin disinfectants Iodine

For disinfection of the skin:

Apply by spraying on the animals' skin (intact) for a topical disinfection:

- dairy and beef cattle on the udder before calving: 1 spray on each teat (equivalent to 4.8 mL per application). Disinfection takes place once, one day before calving and once, one day after calving. The animals should be kept standing on a clean floor for at least 5 minutes
- - sows on the udder before farrowing: 15 to 20 mL per animal, once one day before farrowing and once everyday during 4 days after farrowing. The animals should be kept standing on a clean floor for at least 5 minutes.

Let the product dry on skin.
Only for use on intact skin.
For professional use only. Do not mix with other chemicals.

Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 5.1 – *meta* SPC 5: PT3 – RTU Teat disinfectants PVP-Iodine

Apply the product by dipping or by spraying:
-By dipping: Apply the product with a dip cup. Wash the dip cup with water after use
-By spraying: Apply the product with a manual sprayer or with an automatic sprayer.

Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment.

The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats. The animals should be kept standing for at least 5 minutes.
For professional use only. Do not mix with other chemicals.

Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 6.1 – *meta* SPC 6: PT3 – RTU Skin disinfectants PVP-Iodine

For disinfection of the skin:

- Dairy and beef cattle: Apply the product by spraying on the udder before calving (1 spray / teat equivalent to 4.8 mL per application). Disinfection takes place once, one

day before calving and once, one day after calving. The animals should be kept standing for at least 5 minutes to let the product dry.).

- Sows on the udder before farrowing: Assume 15 to 20 mL per animal, once one day before farrowing and once every day during 4 days after farrowing. The animals should be kept standing on a clean floor for at least 5 minutes.

Only for use on intact skin.
For professional use only. Do not mix with other chemicals.
Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 7.1 – *meta* SPC 7: PT4– Surface disinfectants Iodine

- Use in professional kitchens (PT04) and in food industry (PT04):

The product is diluted before use (according to the table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used in professional kitchens (surface disinfection): Frequency is once per day.
The product is used in food industry (surface disinfection): Frequency is once per day.
The product is applied with a back pulverisator or an automatic sprayer. Spray sufficient liquid to keep the surface wet for at least 15 minutes and rinse the surfaces afterwards with clean water.

Example* for product with 1% iodine	Dilution of the product	Contact time
Bactericidal activity	1.5 *(15 ml product, add water up to 1L)*	15 min
Yeasticidal activity	1.25 *(12.5 ml product, add water up to 1L)*	15 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 1 to 2.5% it is not possible to give all product dilutions here.

For professional use only. Do not mix with other chemicals.
Do not prepare more fluid than necessary. Assume 0.04L solution for every square meter that has to be disinfected.

Use Restrictions:	Not applicable

Use # 7.2 – *meta* SPC 7: PT3 – Surface disinfectants Iodine

- Use in Veterinary field (PT03):

Use in veterinary field (PT3), Surface disinfection:
Product should be diluted with water before use (according to table below).Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used to disinfect animal housings of pigs, cows and poultry.
Apply the product with a back pulverisator or an automatic sprayer in order to cover the surfaces. Respect a contact time (according to table below). Animal housing must be empty of animals during application and re-entry of animals can be done 24h after the end of the application. Rinse the feeders with water after contact time and dry them with paper before fill in them.

Example* for product with 2.5% iodine		Dilution of the product	Contact time
Bactericidal activity		**1% (10ml product, add water up to 1L)*	30 min
Yeasticidal activity		**1% (10ml product, add water up to 1L)*	30 min
Virucidal activity		1.5*% (12ml product, add water up to 1L)*	30 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 1 to 2.5% it is not possible to give all product dilutions here.

For professional use only. Do not mix with other chemicals.
Do not prepare more fluid than necessary. Assume 0.04L solution for every square meter that has to be disinfected.
Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 8.1 – *meta* SPC 8: PT4– Concentrated Surface disinfectants Iodine

- Use in professional kitchens (PT04) and in food industry (PT04):

The product is diluted before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used in professional kitchens (surface disinfection): Frequency is once per day.
The product is used in food industry (surface disinfection). Frequency is once per day.
The product is applied with a back pulverisator or an automatic sprayer. Spray sufficient liquid to keep the surface wet for at least 15 minutes and rinse the surfaces afterwards with clean water.

Example* for product with 3% iodine		Dilution of the product	Contact time
Bactericidal activity		*0.5% (5 ml product,*	15 min

		add water up to 1L)		
Yeasticidal activity		0.4% *(4 ml product, add water up to 1L)*	15 min	

*Each product label should give information on how the dilution should be made. Since the concentration iodine in products within this meta SPC can range from 2.5 to 3% it is not possible to give all product dilutions here.

For professional use only. Do not mix with other chemicals.
Do not prepare more fluid than necessary. Assume 0.04L solution for every square meter that has to be disinfected.

Use Restrictions:	Not applicable

Use # 8.2 – *meta* SPC .8: PT3 – Surface disinfectants Iodine

Use in veterinary field (PT3), Surface disinfection
Product should be diluted with water before use (according to table below).
Clean the surfaces thoroughly with a detergent before disinfection. Rinse with clean water and remove surplus water.
The product is used to disinfect animal housings of pigs, cows and poultry.
Apply the product with a back pulverisator or an automatic sprayer in order to cover the surfaces. Respect a contact time (according to table below). Animal housing must be empty of animals during application and re-entry of animals can be done 24h after the end of the application. Rinse the feeders with water after contact time and dry them with paper before filling them.

Example* for product with 2.5% iodine		Dilution of the product	Contact time
Bactericidal activity		*1% (10ml product, add water up to 1L)*	30 min
Yeasticidal activity		*1% (10ml product, add water up to 1L)*	30 min
Virucidal activity		*1.5% (12ml product, add water up to 1L)*	30 min

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 2.5 to 3% it is not possible to give all product dilutions here

For professional use only. Do not mix with other chemicals.
Do not prepare more fluid than necessary. Make 0.04L solution for every square meter that has to be disinfected.

Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 9.1 – *meta* SPC 9: PT4– CIP disinfectants Iodine

- Disinfection of milking machine

Clean first the CIP installation.
Apply the product in the automatic system with a dilution of the product (according to table below) with water.
Respect a contact time according to the table below.
Rinse the installation with water.
The product is used up to 2 times per day
Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

- Disinfection of CIP installations in Food industry

Clean first the CIP installation.
Apply the product in the automatic system with a dilution of the product (according to table below) with water.
Respect a contact time according to the table below.
Rinse the installation with water.

Example* for product with 1% iodine	Dilution of the product	Contact time
Bactericidal and Yeasticidal activity	0.125 *(1,25 ml product, add water up to 1L)*	5 min. for bacteria 15 min. for yeasts

*Each product label should give information on how the dilution should be made for this product. Since the concentration iodine in products within this meta SPC can range from 0.5 to 1% it is not possible to give all product dilutions here. An example is given for products with 0.5% and 1% iodine

For professional use only. Do not mix with other chemicals.

Use Restrictions:	Not applicable

Use # 10.1 – *meta* SPC 10: PT3 – Concentrated Teat disinfectants Iodine

The product must be diluted before use in order to allow a final concentration of iodine of 0.3% .
. Each product label should give information on how the dilution should be made e.g.:
Product with 2.5% iodine: This product should be diluted to 12% (120 ml product, add water up to 1L).
Product with 3% iodine: This product should be diluted to 10% (100ml product, add water up to 1L).
Since the concentration iodine in products within this meta SPC can range from 2.5 to 3% it is not possible to give all product dilutions here.

Do not prepare more fluid than necessary. Make 5 mL solution per cow per treatment. Use gloves and eye protection during the dilution step. The ready to use solution can be kept and used during 1 week.

Apply the diluted product on the teats with a manual sprayer or with an automatic sprayer. The product should be used directly after milking 2 to 3 times per day by using a manual or automatic sprayer. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats, the animals should be kept standing for at least 5 minutes. For professional use only. Do not mix with other chemicals. Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 11.1 – *meta* SPC 11: PT3 – RTU Teat disinfectants Iodine

Apply the product by dipping or by spraying: *-By dipping:* Apply the product with a dip cup. Wash the dip cup with water after use *-By spraying:* Apply the product with a manual sprayer or with an automatic sprayer. Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The product should be used immediately after each milking, two or three times per day. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats, the animals should be kept standing for at least 5 minutes. For professional use only. Do not mix with other chemicals. Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

Use # 12.1 – *meta* SPC 12: PT3 – RTU Teat disinfectants Iodine

Apply the product by dipping or by spraying: *-By dipping:* Apply the product with a dip cup. Wash the dip cup with water after use *-By spraying:* Apply the product with a manual sprayer or with an automatic sprayer. Do not prepare more fluid than necessary. Assume 5 mL solution per cow per treatment. The product should be used immediately after each milking: 2 times per day for manual spraying and 3 times per day for manual dipping and spraying with robot. Ensure that the teat is completely covered to three quarters of its length. Let the product dry on teats, the animals should be kept standing for at least 5 minutes. For professional use only. Do not mix with other chemicals. Discharge waste water that may contain residues of the product and possible leftovers of diluted fluids to the manure storage or municipal sewer where legally allowed. Do not discharge residues to individual wastewater treatment plants to avoid malfunctioning.

Use Restrictions:	Not applicable

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

MetaSPC's 1, 7 and 10:
After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
If medical advice is needed, have product container or label at hand.
After ingestion: Rinse mouth. Spit. Do NOT induce vomitting and immediately get medical advice.
If medical advice is needed, have product container or label at hand.

MetaSPC 6:
After eye contact: Rinse immediately with water.
After ingestion: Rinse mouth. Spit. Do NOT induce vomitting and immediately get medical advice.
If medical advice is needed, have product container or label at hand.

MetaSPC 8:
After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
If medical advice is needed, have product container or label at hand.
After skin (or hair) contact: Remove contaminated clothing and shoes. Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.
After ingestion: Rinse mouth. Spit. Do NOT induce vomitting and immediately get medical advice.
If medical advice is needed, have product container or label at hand.

MetaSPC 9:
After inhalation: Remove person to fresh air and keep comfortable for breathing. Obtain medical attention if breathing difficulty persists.
After skin (or hair) contact: Remove contaminated clothing and shoes. Wash the affected area thoroughly with plenty of soap and water. Get medical attention if symptoms occur.
After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain emergency medical attention if pain, blinking, tears or redness persist.
After ingestion: Rinse mouth. Do NOT induce vomiting and immediately get medical advice.
If medical advice is needed, have product container or label at hand.

MetaSPC's 2, 3, 4, 5, 11 and 12:
After eye contact: Rinse immediately with water.
After ingestion: Rinse mouth. Spit.

C. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

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

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

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use. Protect from frost. Do not expose to temperatures >40°C. The shelf-life of the products in metaSPCs 1, 2, 3, 4, 6, 7, 8, 9, 10, 11 and 12 is 2 years. The shelf-life of the products in metaSPC 5 is 18 months.

Documentation

A. DATA SUBMITTED IN RELATION TO PRODUCT APPLICATION

Note of the applicant: CID LINES NV is a member of the Iodine Registration group. A letter of access has been attached in section 13 of the Iuclid file. Therefore we have access to the complete dossier for the approval of the active substance Iodine (including polyvinylpyrrolidone iodine).

For the list of new data submitted in support of the evaluation of the active substance and the list of data submitted in support of the evaluation of the biocidal product family, please refer to annex I.

B. ACCESS TO DOCUMENTATION

CID LINES NV is a member of the Iodine Registration group. A letter of access has been attached in section 13 of the Iuclid file. Therefore we have access to the complete dossier for the approval of the biocidals active substance Iodine (including polyvinylpyrrolidone iodine).

C. SIMILAR CONDITIONS OF USE

Following the pre-submission procedure of ECHA, it has been concluded that the biocidal product family Iodine based products — CID LINES NV is deemed to be eligible for Union authorisation.

Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation.
No objections were raised from either the Commission or the Member States Competent Authorities (MSCA5) as regards the eligibility of the prospective application for Union

authorisation on the grounds that the biocidal product family Iodine based products — CID LINES NV falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union.

Other information

Application codes: Communication number of the outcome of the consultation during the pre-submission phase: D(2015)2137

2.3 ASSESSMENT OF THE BIOCIDAL PRODUCT FAMILY

Physical, chemical and technical properties

The data presented below is reported per meta SPC. In the confidential annex (separate document), the eCA has included additional discussion on e.g. iodine content stability during storage as well as considerations with regard to the proposed compositions of the meta SPCs and their acceptability.

The following table contains information on which products belong to which meta SPC:

Meta SPC	Product code	Product name	Formulation type
1	1.1	Kenodin SD 400	SL
2	2.1	KENODIN	AL
	2.2	KENODIN FILM	AL
3	3.1	ANIMAL SKIN DISINFECTANT	AL
	3.2	DERMADES	AL
4	4.1	KENODIN SD (F13)	AL
5	5.1	Iodo PVP	AL
	5.2	Iodo SD PVP	AL
6	6.1	Dermades PVP	AL
7	7.1	Dodin 20	SL
8	8.1	Iocid 30	SL
9	9.1	Iodo CIP	SL
10	10.1	Kenodin SD 900	SL
11	11.1	KENODIN 2500	AL
12	12.1	KENODIN 5000	AL
	12.2	KENODIN SD5000	AL

For the model formulations used for testing, more detailed information on the composition of these formulations is included in the confidential annex.

Stability data –analytical method
In the storage stability studies, the pharmacopoeia method is used. Please refer to the section *methods for detection and identification* for validation data.

Stability data – active substance increase
In some storage stability studies, an increase in iodine was observed. An explanation for the observations is included in the confidential annex to the PAR.

Stability data – Breakdown products
Considering in various storage stability studies, the iodine content declined by more than 10%, it is required to investigate whether, in addition to whether the product is still efficacious, any compounds are formed that may influence the risk assessment, e.g. hazardous metabolites.

Iodine is an oxidiser and behaves similarly to chlorine and bromine. Generally, iodine oxidises a compound, resulting in the formation of iodide and an oxidised compound. Iodide is taken into account in the risk assessment as this is based on the sum of the total iodine concentration (by breaking down, the total amount of iodine is not changed). The oxidised compounds are expected to be hard to identify and unlikely to pose a significant risk. The eCA therefore considers further work to identify breakdown products should not be necessary.

Stability data – Packaging stability
The storage stability trials support the proposed shelf-life. However, the studies do not contain detailed information about the stability of the packaging itself, as the appearance / seepage of the packaging is not reported. This is a deficiency and although HDPE is a common packaging material, this issue should be addressed upon renewal of the authorization. The applicant should then submit the appropriate data to show that packaging remains stable during storage. The issue was provisionally addressed by a confirmation by the lab that no deformation or other degradation of the packaging was observed during the trials.

Stability data –Acidity after storage
In addition to the packaging stability, for a small number of products, the acidity after storage should have been determined. Considering this data is not ciritical to the risk assessment and not used for classification and labelling in this case, the data can be provided at the renewal of the product family authorization.

Meta SPC 1

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 1.1	liquid	Kenodin SD 400 – analysis, [redacted], 2015, 5/1.10.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 1.1	Dark brown	Kenodin SD 400 – analysis, [redacted], 2015, 5/1.10.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 1.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 1.1	5.49 at 20.5°C	Kenodin SD 400 – analysis, [redacted], 2015, 5/1.10.1
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The value reported for the pH is a specification, not an actual measurement. The reported				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
pH of KENODIN SD 400 is 5.49 at 20.5°C. Acidity data is not considered required for this meta SPC.				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 1.1	1.081 g/cm³ at 20.5°C	Kenodin SD 400 – analysis, [redacted], 2015, 5/1.10.1
The value reported for the density is a specification, not an actual measurement. The reported density of KENODIN SD 400 is 1.081 g/cm^3 at 20.5°C.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substances are formula Kenodin SD 400 and Kenodin SD 900	Formula Kenodin SD 400 Formula Kenodin SD 900	Storage stability tests of meta SPC 1, Cirlam Laboratory, 3.4.1/1.1

eCA remarks
The following accelerated storage stability was submitted:

KENODIN SD 900 (meta SPC 10) stored for 8 weeks at 40°C in HDPE (1L)

Time	Initial	4 weeks	8 weeks
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.72	5.58	5.66
Density	1.100	1.103	1.106
%Iodine (%increase)	2.773	3.107 (+12.0)	3.120 (+12.5)

KENODIN SD 400 (meta SPC 1) stored for 8 weeks at 40°C in HDPE (1L)

Time	Initial	4 weeks	8 weeks
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.93	5.31	5.22
Density	1.114	1.116	1.111
%Iodine (%increase)	1.477	1.586 (+7.4)	1.674 (+13.3)

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substances are formula Kenodin SD 400 and Kenodin SD 900	Formula Kenodin SD 400 Formula Kenodin SD 900	Storage stability tests of meta SPC 1, Cirlam Laboratory, 3.4.1/1.1

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

eCA remarks
The following shelf-life data is now available, showing the active substance content does not decrease during the storage period:

Stability data at 25°C in HDPE of KENODIN SD900 (Meta SPC10):

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.72	5.76	5.58	5.74	5.81	5.51	5.12
Density	1.100	1.104	1.104	1.105	1.104	1.103	1.103
%Iodine (%increase)	2.773 (-)	2.939 (+6.0)	2.974 (+7.2)	3.065 (+10.5)	3.017 (+8.8)	3.000 (+8.2)	3.017 (+8.8)

Stability data at 25°C in HDPE of Meta SPC 1 KENODIN SD400 (Meta SPC 1):

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.93	5.40	5.48	5.47	5.48	5.29	4.79
Density	1.114	1.115	1.118	1.115	1.114	1.115	1.115
%Iodine (%increase)	1.477 (-)	1.480 (+0.2)	1.581 (+7.0)	1.642 (+11.2)	1.678 (+13.6)	1.667 (+12.9)	1.606 (+8.7)

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substances are formula Kenodin SD 400 and Kenodin SD 900	Formula Kenodin SD 400 Formula Kenodin SD 900	Storage stability tests of meta SPC 1, Cirlam Laboratory, 3.4.1/1.1

eCA remarks
Low temperature storage data was submitted, summarised by the eCA:

KENODIN SD900 (meta SPC10) stored for 8 weeks at 5°C in HDPE

Time	Initial	4 weeks	8 weeks
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.72	5.75	5.82
Density	1.100	1.105	1.110
%Iodine (%increase)	2.773 (-)	2.823 (+1.8)	2.971 (+7.1)

KENODIN SD400 (meta SPC 1) stored for 8 weeks at 5°C in HDPE

Time	Initial	4 weeks	8 weeks
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
pH	4.93	5.30	5.39	
Density	1.114	1.117	1.117	
%Iodine (%increase)	1.477 (-)	1.377 (-6.8)	1.398 (-5.3)	
The products tested are considered stable at 5°C. However, the tests should be performed at 0°C to negate the need of the a storage restriction for low temperatures. The storage conditions require the restriction 'Protect from frost'.				
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	/	/	Not relevant as the commercial packagings are not transparent Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substances are formula Kenodin SD 400 and Kenodin SD 900	Formula Kenodin SD 400 Formula Kenodin SD 900	Storage stability tests of meta SPC 1, Cirlam Laboratory, 3.4.1/1.1
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 1, Cirlam Laboratory, 3.4.1/1.1
Wettability	/	/	Not relevant because	Guidance on the BPR, Volume I: Identity/physico

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the product is a liquid.	-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico -chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico -chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico -chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not	Guidance on the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			relevant because the product is a liquid.	BPR, Volume I: Identity/physico -chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico -chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	CIPAC MT 47.2	The test substance is the Formula 2 with 3% Iodine and the maximum of all excipients in meta SPC 1	According to the results of the foam test performed according to CIPAC MT 47.2 method, MetaSPC 1 presents a remaining quantity of foam of 42 mL after 60 seconds.	Foam test of Formula 2 according to CIPAC MT 47.2, Antczak, S, 2015, 3.5/1.1
	CIPAC MT 47.1	KENODIN SD 400 Batch S512704	20% in CIPAC D water: 140 mL foam after 1 minute 50 mL foam after	Platteau, J, 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			12 minutes	
eCA remark 20mL of the model formulation 2 was added to CIPAC C water (1%v/v). Formula 2 represents the highest level of surfactant within this meta SPC. At the highest proposed in-use concentration of KENODIN SD 400 (meta SPC 1), foaming exceeds the 60 mL threshold. Based on the risk assessment the following PPE are already prescribed: eye protection, protective clothing and gloves. This is considered sufficient to address issues with the risk to the operator.				
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke	/	/	Not	Guidance on the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
generators			relevant because there is no generation of smoke when using the products as described on the labels	BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	CIPAC MT 41	The test substance is the	The tested product forms a	Dilution test of BPF Iodine according to

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		formulation Kenodin SD 400 at the maximum in-use concentration (20%)	stable aqueous dilution	CIPAC MT 41, Platteau, J., 2018, 3.4.1/1.1

eCA remark

The applicant has generated CIPAC MT41 based data on dilutions, stored for one week (rather than 18 or 24h). Products were diluted in tap water and CIPAC water type C to approximately 0.3% iodine (3000ppm).

Stability data at 25°C in solution of KENODIN SD 400 in water C (20%v/v):

Time	Initial	1w
Appearance	Dark brown liquid	Dark brown liquid
pH	5.27	5.32
Density	1.020	1.020
%Iodine	0.301 (-)	0.305 (+3.1%)

Stability data at 25°C in solution of KENODIN SD 400 in tap water (20%v/v):

Time	Initial	1w
Appearance	Dark brown liquid	Dark brown liquid
pH	6.05	5.99
Density	1.022	1.022
%Iodine	0.309 (-)	0.299 (-3.2%)

Stability data at 25°C in solution of KENODIN SD 900 in water C (11%v/v):

Time	Initial	1w
Appearance	Dark brown liquid	Dark brown liquid
pH	5.20	5.37
Density	1.010	1.010
%Iodine	0.304 (-)	0.337 (+10.9%)

Stability data at 25°C in solution of KENODIN SD 900 in tap water (11%v/v):

Time	Initial	1w
Appearance	Dark brown liquid	Dark brown liquid
pH	6.77	6.62
Density	1.011	1.011
%Iodine	0.350 (-)	0.328 (-6.3%)

Dilutions of the products of Meta SPC 1 (KENODIN SD 400) and 10 (KENODIN SD 900) were tested, showing most formulations are stable. Exceptions is model formula 3 (>10% decrease). Considering the meta SPC 1 was revised to only include one formulation (KENODIN SD400), the data on formula 3 can be ignored for meta SPC1.

The dilution stability representative for the use of the product was tested, including after storage in the studies Platteau 2019 and 2019a, which are reported in the table of meta SPC 7, including a justification for read-across.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Surface tension	OECD 115	Kenodin SD 400 Kenodin SD 900	Kenodin SD 400 has a surface tension of 29.47 mN/m at 20°C and diluted at 20% v/v. Kenodin SD 900 has a surface tension of 29.98 mN/m at 20°C and diluted at 11% v/v.	Study report of the ENSCL (07.05.2018)
Viscosity	OECD 114 (rotational viscometer)	KENODIN SD 400 Batch 5118500001	At 20°C 76 mPa.s At 40°C 72 mPa.s Shear rate not indicated.	Platteau, J, 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

Meta SPC 2

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 2.1	liquid	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	Visual	The test substance is the formulation of SPC 2.2	liquid	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	Visual	The test substance is the formulation of SPC 2.3	liquid	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	Visual	The test substance is the formulation of SPC 2.4	liquid	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 2.1	Dark brown	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	Visual	The test substance is the formulation of SPC 2.2	Dark brown	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	Visual	The test substance is the formulation of SPC 2.3	Dark brown	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	Visual	The test substance is the formulation of SPC 2.4	Dark brown	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 2.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 2.2	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 2.3	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 2.4	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 2.1	5.69 at 21°C	Kenodin – analysis, [redacted], 2015,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				5/1.2.1
	CIPAC MT 75.3	The test substance is the formulation of SPC 2.2	3.99 at 22°C	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	CIPAC MT 75.3	The test substance is the formulation of SPC 2.3	5.52 at 24.5°C	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	CIPAC MT 75.3	The test substance is the formulation of SPC 2.4	5.39 at 22.5°C	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The reported pH values are specifications. The actual measurements fall within this range. One of the products, Kenodin Film, has a pH of slightly below 4: 3.99 at 22°C, which formally means the acidity should be determined. The same formulation was tested for stability and the pH at the initial time stamp was above 4, but after storage, the pH decreased to below 4. Formulation 1.2.1: 5.56 Formulation 1.2.2: 3.99 Formulation 1.2.3: 5.52 Formulation 1.2.4: 5.39				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 2.1	1.041 g/cm³ at 20.5°C	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	OECD Test guideline 109	The test substance is the formulation of SPC 2.2	1.041 g/cm³ at 21.0°C	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	OECD Test guideline 109	The test substance is the formulation of SPC 2.3	1.035 g/cm³ at 19.0°C	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	OECD Test guideline 109	The test substance is the formulation of SPC 2.4	1.032 g/cm³ at 19.0°C	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
eCA remark The density values are specified ranges, not actually determined values. The actual measurements are: 1.041g/cm^3 at 20.5°C, 1.041 g/cm^3 at 21.0°C, 1.035 g/cm^3 at 19.0°C				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
and 1.032 g/cm^3 at 19.0°C respectively.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 2.1, 2.2, 2.3, 2.4 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	Please see the eCA summary below.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark

Meta SPC 2 formula F110, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.54	4.58	4.69
Density	1.016	1.015	1.015
%Iodine (%increase)	0.284 (-)	0.296 (+4.2)	0.286 (+0.7)

Meta SPC 2 formula F6, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.51	4.78
Density	1.058	1.057	1.054
Viscosity (mPa.s, 10rpm)	2940	2710	2550
%Iodine (%increase)	0.522 (-)	0.530 (+1.5)	0.469 (-10.2)

Meta SPC 2 KENODIN, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.48	5.48
Density	1.037	1.038	1.039
Viscosity (mPa.s, 10rpm)	2000	3260	3820
%Iodine (%increase)	0.299 (-)	0.321 (+7.36)	0.339 (+13.4)

Meta SPC 2 KENODIN FILM, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	3.80	3.64
Density	1.028	1.023	1.027
Viscosity (mPa.s, 10rpm)	2972	2168	2316
%Iodine (%increase)	0.302	0.293 (-3.2%)	0.264 (-12.6%)

Meta SPC 2 KENODIN 5000, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.13	5.42
Density	1.032	1.033	1.036
Viscosity (mPa.s, 10rpm)	2000	4520	4730
%Iodine (%increase)	0.500	0.451 (-9.8)	0.489 (-2.2)

Meta SPC 2 KENODIN SD5000, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.31	5.01
Density	1.034	1.030	1.032
%Iodine (%increase)	0.530 (-)	0.496 (-6.9)	0.471 (-11.1)

Meta SPC 2 formula F8, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.00	4.82
Density	1.017	1.017	1.017
%Iodine (%increase)	0.473 (-)	0.443 (-6.3)	0.412 (-12.9)

Meta SPC 2 KENODIN 2500, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.38	5.23	4.97
Density	1.016	1.036	1.038
%Iodine (%increase)	0.244 (-)	0.269 (+10.2)	0.271 (+11.1)
Viscosity (mPa.s)	2460	2170	2150

Meta SPC 2 formula F7, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.66	5.77
Density	1.028	1.025	1.036
%Iodine (%increase)	0.261 (-)	0.280 (+7.3)	0.282 (+8.0)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Viscosity (mPa.s)	2420	2360	2120	

The active substance content decreased by more than 10% from the initial content for some formulations. Efficacy data was generated, which is included in the confidential annex.

The applicant has also indicated that errors occurred during some studies and they were therefore restarted. What these errors are exactly was not indicated. Therefore, the eCA cannot assess what the consequence of these errors should be. All data is summarised above and the eCA has not found any reason for concern with regard to the validity of the test results.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 2.1, 2.2, 2.3, 2.4 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	Please see the eCA summary below.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark

The applicant has provided the data reported below. However, they have also indicated that errors occurred during some studies and they were therefore restarted. All data is summarised above and the eCA has not found any reason for concern with regard to the validty of the test results.

Some products showed a decrease in active substance content of >10%. This decrease was addressed using efficacy data. See the confidential annex (paragraph 3.4) for details on tested formulations and concentrations.

When the active substance degrades by more than 10%, the influence of such degradation with regard to hazard should be addressed. Considering iodine is a non-specific oxidiser, it is considered acceptable that the breakdown products are not identified. The breakdown products should be iodide ions and oxidised material. What compounds are formed is difficult to identify. It is not expected any specific hazardous compounds are formed in the process.

Meta SPC 2 formula F5, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.14	4.94	5.02	4.84	4.82	4.75
Density	1.016	1.014	1.015	1.014	1.015	1.016	1.015

Property	Guideline and Method	Purity of the test substance (% (w/w)		Results		Reference	
%Iodine (%increase)	0.268 (-)	0.259 (-3.4)	0.258 (-3.7)	0.252 (-6.0)	0.248 (-7.5)	0.244 (-9.0)	0.242 (-9.7)

Meta SPC 2 formula F6, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.67	5.61	5.60	5.30	5.02	4.93
Density	1.058	1.061	1.062	1.063	1.062	1.063	1.061
Viscosity (mPA.s, 10rpm)	2940	2770	3110	3130	3110	3290	3970
%Iodine (%increase)	0.522 (-)	0.562 (+7.7)	0.575 (+10.2)	0.527 (+0.96)	0.539 (+3.3)	0.472 (-9.6)	0.469 (-10.2)

Meta SPC 2 KENODIN, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.73	5.70	5.63	5.66	5.61	5.08
Density	1.037	1.039	1.039	1.040	1.039	1.039	1.038
Viscosity (mPA.s, 10rpm)	2000	1560	1560	2116	1510	1620	2290
%Iodine (%increase)	0.299 (-)	0.314 (+5.0)	0.318 (+6.4)	0.333 (+11.4)	0.333 (+11.4)	0.321 (+7.4)	0.281 (-6.0)

Meta SPC 2 KENODIN FILM, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	3.99	3.98	3.88	3.72	3.54	3.52
Density	1.028	1.027	1.027	1.029	1.027	1.027	1.027
Viscosity (mPA.s, 10rpm)	2972	2648	2649	2620	2284	2308	2630
%Iodine (%increase)	0.302 (-)	0.286 (-5.3)	0.286 (-5.3)	0.271 (-10.3)	0.270 (-10.6)	0.277 (-8.3)	0.275 (-8.9)

Meta SPC 2 KENODIN 5000, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid

Property	Guideline and Method	Purity of the test substance (% (w/w)		Results		Reference	
pH	5.45	5.61	5.59	5.55	5.54	5.56	5.35
Density	1.032	1.036	1.036	1.036	1.037	1.037	1.036
Viscosity (mPA.s, 10rpm)	2000	2280	2330	2100	2330	2360	2480
%Iodine (%increase)	0.500 (-)	0.479 (-4.2)	0.485 (-3.0)	0.487 (-2.6)	0.480 (-4.0)	0.475 (-5.0)	0.479 (-4.2)

Meta SPC 2 KENODIN SD5000, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.25	5.12	5.49	5.00	4.78	4.63
Density	1.034	1.031	1.032	1.039	1.032	1.033	1.032
%Iodine (%increase)	0.530 (-)	0.523 (-1.3)	0.517 (-2.5)	0.491 (-7.4)	0.491 (-7.4)	0.465 (-12.3)	0.458 (-13.6)

Meta SPC 2 Formula F8, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.18	5.08	5.01	4.80	4.74	4.68
Density	1.017	1.017	1.018	1.018	1.018	1.018	1.018
%Iodine (%increase)	0.473 (-)	0.446 (-5.7)	0.446 (-5.7)	0.434 (-8.3)	0.440 (-7.0)	0.428 (-9.5)	0.427 (-9.7)

Meta SPC 2 KENODIN 2500, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.38	5.23	5.41	5.34	5.41	5.37	5.37
Density	1.016	1.039	1.026	1.021	1.021	1.021	1.021
%Iodine (%increase)	0.264 (-)	0.274 (+16.4)	0.275 (+4.2)	0.274 (+3.8)	0.279 (+5.7)	0.276 (+4.6)	0.274 (+3.8)
Viscosity (mPa.s)	2460	2240	2212	2250	1952	2220	2112

Formulation KENODIN 2500 was moved to meta SPC 11.

Meta SPC 2, formula 7, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

pH	5.50	5.97	5.92	5.93	5.84	5.36	4.95
Density	1.028	1.036	1.036	1.037	1.037	1.038	1.037
%Iodine (%increase)	0.261 (-)	0.279 (+6.9)	0.282 (+8.1)	0.286 (+9.6)	0.284 (+8.8)	0.259 (-0.77)	0.244 (-6.5)
Viscosity (mPa.s)	2420	2486	2726	2368	2348	2950	2080

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 2.1, 2.2, 2.3, 2.4 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	Please see the eCA summary below.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark

Meta SPC 2 formula F5, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.19	5.32
Density	1.016	1.015	1.015
%Iodine (%increase)	0.268	0.266 (-0.75)	0.268 (+0)

Meta SPC 2 formula F6, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.64	5.75
Density	1.058	1.055	1.053
Viscosity (mPa.s, 10rpm)	2940	2910	2490
%Iodine (%increase)	0.522 (-)	0.539 (+3,3)	0.540 (+3.4)

Meta SPC 2 KENODIN, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.79	5.93
Density	1.037	1.039	1.038
Viscosity (mPa.s, 10rpm)	2000	3520	4230
%Iodine (%increase)	0.299 (-)	0.299 (+0)	0.338 (+13.0)

Meta SPC 2 KENODIN FILM, stored 8 weeks at 5°C in HDPE

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	4.31	4.19
Density	1.028	1.028	1.027
Viscosity (mPa.s, 10rpm)	2972	2900	2864
%Iodine (%increase)	0.302	0.295 (-2.3)	0.302 (-)

Meta SPC 2 KENODIN 5000, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.58	5.72
Density	1.032	1.037	1.036
Viscosity (mPa.s, 10rpm)	2000	4352	4520
%Iodine (%increase)	0.500 (-)	0.510 (+2.0)	0.480 (-4.0)

Meta SPC 2 KENODIN SD5000, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.42	5.48
Density	1.034	1.034	1.032
%Iodine (%increase)	0.530 (-)	0.537 (1.3)	0.520 (-1.9)

Meta SPC 2 formula F8, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.32	5.27
Density	1.017	1.018	1.018
%Iodine (%increase)	0.473 (-)	0.485 (+2.5)	0.470 (-0.63)

Meta SPC KENODIN 2500, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.38	5.31	5.17
Density	1.016	1.035	1.039
%Iodine (%increase)	0.244 (-)	0.251 (+2.9)	0.258 (+5.7)
Viscosity (mPa.s)	2460	2210	2270

Formulation KENODIN 2500 was moved to meta SPC 11.

Meta SPC formula F7, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
pH	5.50	5.80	6.14	
Density	1.028	1.038	1.040	
%Iodine (%increase)	0.261 (-)	0.267 (+2.3)	0.265 (+1.5)	
Viscosity (mPa.s)	2420	2330	2080	
The products tested are considered stable at 5°C. However, the tests should be performed at 0°C to negate the need of the a storage restriction for low temperatures. The storage conditions require the restriction 'Protect from frost'.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 2.1, 2.2, 2.3, 2.4 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See shelf-life data	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physic

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				o-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor doesn't need to be diluted with water.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology –

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are	Guidance on the BPR, Volume I:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			not aerosol	Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water	CID LINES
Surface tension	/	/	Kenodin SD 5000 has a surface tension of 29.86 mN/m at 20°C at 100% v/v. Kenodin, Kenodin Film and Kenodin 5000 have a dynamic viscosity more than 200 mPa/s. According to the OECD 115 it is clearly stated under 'Initial Considerations'	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			that measurement of surface tension is restricted to aqueous solutions with a dynamic viscosity of less than 200 mPa.	
Viscosity	OECD Test guideline 114	The test substance is the formulation of SPC 2.1	1500-6000 mPa.s	Kenodin – analysis, Chenu, J., 2015, 5/1.2.1
	OECD Test guideline 114	The test substance is the formulation of SPC 2.2	2000-6000 mPa.s	Kenodin Film – analysis, Chenu, J., 2015, 5/1.2.2
	OECD Test guideline 114	The test substance is the formulation of SPC 2.3	1500-6000 mPa.s	Kenodin 5000 – analysis, Chenu, J., 2015, 5/1.2.3
	OECD 114 (rotational viscometer)	F05 Batch 5118500002 F06 Batch 5117420005	At 20°C <10 mPa.s At 40°C <10 mPa.s At 20°C 1870 mPa.s At 40°C 1348 mPa.s Shear rate not indicated.	Platteau, J, 2019

eCA remark
The applicant reasons surface tension data is not required considering the product's viscosity. The eCA considers that the reasoning is acceptable. The ring method will become less accurate with increasing viscosity. Based on the composition of this meta SPC, the product is expected to be surface active as it contains a significant amount of surfactants.

For the viscosity, acceptable data is available. The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.

metaSPC 3

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 3.1	liquid	Animal Skin Disinfectant – analysis, [redacted], 2015, 5/1.3.1
	Visual	The test substance is the formulation of SPC 3.2	liquid	Dermades – analysis, [redacted], 2015, 5/1.3.2
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 3.1	Dark brown	Animal Skin Disinfectant – analysis, [redacted], 2015, 5/1.3.1
	Visual	The test substance is the formulation of SPC 3.2	Dark brown	Dermades – analysis, [redacted], 2015, 5/1.3.2
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 3.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 3.2	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 3.1	5.49 at 22°C	Animal Skin Disinfectant – analysis, [redacted], 2015, 5/1.3.1
	CIPAC MT 75.3	The test substance is the formulation of SPC 3.2	5.70 at 21°C	Dermades – analysis, [redacted], 2015, 5/1.3.2
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The reported pH values are specifications. The actual measurements fall within this range: 5.49 at 22°C and 5.70 at 21°C respectively.				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 3.1	1.038 g/cm³ at 21°C	Animal Skin Disinfectant – analysis, [redacted], 2015, 5/1.3.1

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	OECD Test guideline 109	The test substance is the formulation of SPC 3.2	1.049 g/cm³ at 21°C	Dermades – analysis, [redacted], 2015, 5/1.3.2
eCA remark The reported (relative) densities are specifications. The actual measurements fall within this range: 1.038 g/cm^3 at 21°C and 1.049 g/cm^3 at 21°C respectively.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 3.1, 3.2 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See eCA summary	Storage stability tests of meta SPC3, Cirlam Laboratory, 3.4.1/1.3

eCA remark

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F9

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.12	5.23	5.26
Density	1.038	1.038	1.038
%iodine (%increase)	0.300 (-)	0.314 (+4.7)	0.319 (+6.3)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F10

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.06	5.44	5.32
Density	1.036	1.059	1.055
%iodine (%increase)	0.995 (-)	1.103 (+10.9)	0.856 (-14.0)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F11

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.41	5.52	5.44
Density	1.048	1.045	1.042
%iodine (%increase)	0.304 (-)	0.338 (+11.1)	0.343 (+12.8)

Storage at 40°C for 8 weeks in HDPE (1L) – ANIMAL SKIN DISINFECTANT

	Initial	4w	8w

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.32	5.41
Density	1.039	1.037	1.037
%iodine (%increase)	0.299 (-)	0.300 (+0.3)	0.324 (+8.0)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F12

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.94	4.34	4.45
Density	1.040	1.042	1.040
%iodine (%increase)	1.001 (-)	0.931 (-7.0)	0.984 (-1.7)

Storage at 40°C for 8 weeks in HDPE (1L) – DERMADES

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.40	5.41	5.37
Density	1.052	1.048	1.050
%iodine (%increase)	1.002 (-)	1.107 (+10.5)	1.104 (+10.2)

The storage data shows that products within this meta SPC may have its iodine content decrease by more than 10% from the initial content. Efficacy data was provided showing a decrease of 14% in the active substance content does not negatively affect the efficacy of the products. See the confidential annex (paragraph 3.4) for details on details on tested formulations and concentrations.

The eCA cannot fully explain why the model formulation no. 11 has a very different stability compared to no. 10. The only difference between these formulations is the active substance content. The other model formulation with the high active substance content also shows a decrease in active substance content, although not exceeding 10%. The effects may be caused by the ratio between the stabiliser(s) and the active substance, but there is too little evidence supporting this. Considering the decrease observed is covered by efficacy data, the eCA accepts that there is no further justification for the observed results.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 3.1, 3.2 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See eCA summary	Storage stability tests of meta SPC 3, Cirlam Laboratory, 3.4.1/1.3

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

eCA remark
The following shelf-life data is available:

Storage at 25°C for 2 years in HDPE (1L) – Formula F9

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.12	5.39	5.36	5.52	5.46	5.40	5.32
Density	1.038	1.038	1.038	1.039	1.036	1.039	1.038
%iodine (%increase)	0.300 (-)	0.330 (+10)	0.319 (+6.3)	0.324 (+8.0)	0.329 (+9.7)	0.320 (+6.7)	0.309 (+3.0)

Storage at 25°C for 2 years in HDPE (1L) – Formula F10

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.06	5.69	5.61	5.67	5.57	5.17	4.69
Density	1.036	1.053	1.026	1.055	1.053	1.054	1.048
%iodine (%increase)	0.995 (-)	1.068 (+7.3)	1.115 (+12.1)	1.084 (+8.9)	1.065 (+7.0)	0.932 (-6.3)	0.925 (-7.0)

Storage at 25°C for 2 years in HDPE (1L) – Formula F11

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.41	5.72	5.68	5.81	5.72	5.65	5.56
Density	1.048	1.047	1.047	1.049	1.048	1.049	1.047
%iodine (%increase)	0.304 (-)	0.346 (+13.8)	0.343 (+12.8)	0.332 (+9.2)	0.321 (+5.6)	0.331 (+8.9)	0.333 (+9.5)

Storage at 25°C for 2 years in HDPE (1L) – ANIMAL SKIN DISINFECTANT

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.53	5.43	5.63	5.60	5.52	5.32
Density	1.039	1.038	1.038	1.038	1.038	1.039	1.038
%iodine (%increase)	0.299 (-)	0.323 (+8.0)	0.323 (+8.0)	0.322 (+7.7)	0.325 (+8.7)	0.322 (+7.7)	0.315 (+5.4)

Storage at 25°C for 2 years in HDPE (1L) – Formula F12

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.94	4.43	4.50	4.51	4.52	4.46	4.20
Density	1.040	1.042	1.039	1.040	1.040	1.038	1.040
%iodine (%increase)	1.001 (-)	0.913 (-8.8)	0.946 (-5.5)	0.918 (-8.3)	0.893 (-10.8)	0.918 (-8.3)	1.020 (+1.9)

Storage at 25°C for 2 years in HDPE (1L) – DERMADES

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.40	5.67	5.57	5.70	5.60	5.27	5.74
Density	1.052	1.050	1.049	1.038	1.039	1.050	1.051
%iodine (%increase)	1.002 (-)	1.099 (+9.7)	1.063 (+6.1)	1.114 (+11.2)	1.132 (+13.0)	1.007 (+0.5)	1.091 (+8.9)

For all products, including the model formulation, the active substance degradation generally did not exceed 10%. The only exception was dummy formulation 12, showed a decreased of slightly over 10% after 12 months, after which the active substance content raised to an acceptable limit. Considering the actual products (not taking into account the model formulations) in the meta SPC all showed good stability, the eCA considers the overall dataset sufficient to support a shelf-life of 24 months for meta SPC 3.

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 3.1, 3.2 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See eCA summary	Storage stability tests of meta SPC 3, Cirlam Laboratory, 3.4.1/1.3

eCA remark
The following low temperature stability data is available:

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F9

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.12	5.19	5.30

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Density	1.038	1.038	1.039
%iodine (%increase)	0.300 (-)	0.325 (+8.3)	0.321 (+7.0)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F10

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.06	5.55	5.67
Density	1.036	1.059	1.055
%iodine (%increase)	0.995 (-)	1.062 (+6.7)	1.057 (+6.2)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F11

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.41	5.63	5.68
Density	1.048	1.052	1.041
%iodine (%increase)	0.304 (-)	0.314 (+3.3)	0.325 (+6.9)

Storage at 5°C for 8 weeks in HDPE (1L) – ANIMAL SKIN DISINFECTANT

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.41	5.63	5.68
Density	1.048	1.052	1.041
%iodine (%increase)	0.299 (-)	0.320 (+7.0)	0.279 (-6.7)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F12

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.94	3.95	4.08
Density	1.040	1.043	1.041
%iodine (%increase)	1.001 (-)	0.856 (-14.5)	0.856 (-14.5)

Storage at 5°C for 8 weeks in HDPE (1L) – DERMADES

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.40	5.50	5.67
Density	1.052	1.049	1.050
%iodine (%increase)	1.002 (-)	1.101 (+9.9)	1.135 (+13.3)

The applicant has proposed to add storage restrictions, based on the outcome of the study with model formulation 12. However, what these conditions should be is unclear. The FAO/WHO manual implies that the determination of the active substance is not a requirement for low temperature stability, as most substance are more stable at lower temperatures. However, in the case of the iodine products, the effectivity of stabilisers

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
may be affected by temperature. To address the concerns related to these observations, the applicant has added the storage restriction "Protect from frost". Efficacy data was provided showing that a decrease of 14.5% in the active substance content does not negatively affect the efficacy of the products.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 3.1, 3.2 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See shelf-life data	Storage stability tests of meta SPC 3, Cirlam Laboratory, 3.4.1/1.3
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 3, Cirlam Laboratory, 3.4.1/1.3
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the	Guidance on the BPR,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			product is a liquid.	Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor doesn't need to be diluted with water.	/
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no	Guidance on the BPR, Volume I:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			generation of smoke when using the products as described on the labels	Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water.	CID LINES
Surface tension		/	Animal Skin disinfectant has a surface tension of 30.71 mN/m at 20°C and at 100% v/v. Dermades has a surface tension of 31.60 mN/m at 20°C and at 100% v/v.	ENSCL study report 07.05.2018.
Viscosity	OECD 114 (rotational viscometer)	F09 Batch 5118500003 F10 Batch 5118500004	At 20°C 76 mPa.s At 40°C 72 mPa.s At 20°C 76 mPa.s At 40°C 72 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency.				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 4

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 4.1	liquid	Kenodin SD – analysis, [redacted], 2015, 5/1.4.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 4.1	Dark brown	Kenodin SD – analysis, [redacted], 2015, 5/1.4.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 4.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 4.1	5.61 at 20.5°C	Kenodin SD – analysis, [redacted], 2015, 5/1.4.1
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The pH reported is a specification, not an actual measurement. The pH measured was 5.61 at 20.5°C.				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 4.1	1.038 g/cm³ at 20.5°C	Kenodin SD – analysis, [redacted], 2015, 5/1.4.1
eCA remark The (relative) density reported is a specification, not an actual measurement. The density measured was 1.038 g/cm^3 at 20.5°C.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 4.1 (pure) (no range, because only one formula in this meta SPC)	See eCA summary	Storage stability tests of meta SPC 4, Cirlam Laboratory, 3.4.1/1.4

eCA remark

Storage at 40°C for 8 weeks in HDPE (1L) – KENODIN SD (formula F13)

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.28	5.31	5.43
Density	1.030	1.036	1.037
%iodine	0.290	0.297	0.305

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
(%increase)	(-)	(+2.4)	(+5.2)	

The iodine content during storage does not change by more than 10% relative to the initial content. Considering the meta SPC does not allow much variation in product composition, a single study is considered acceptable.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 4.1 (pure) (no range, because only one formula in this meta SPC)	See eCA summary	Storage stability tests of meta SPC 4, Cirlam Laboratory, 3.4.1/1.4

eCA remark
The following shelf-life data was submitted:

Storage at 25°C for 2 years in HDPE (1L) – KENODIN SD (formula F13)

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.28	5.61	5.61	5.59	5.48	5.65	5.50
Density	1.030	1.036	1.037	1.037	1.037	1.038	1.036
%iodine (%increase)	0.290 (-)	0.298 (+2.8)	0.299 (+3.1)	0.301 (+3.8)	0.306 (+5.5)	0.306 (+5.5)	0.304 (+4.8)

Considering the narrow ranges of the meta SPC specification, a single study is considered sufficient to allow the conclusion that the products within meta SPC 4 will be stable for 2 years in HDPE.

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 4.1 (pure) (no range, because only one formula in this meta SPC)	See eCA summary	Storage stability tests of meta SPC 4, Cirlam Laboratory, 3.4.1/1.4

eCA remark

Storage at 5°C for 8 weeks in HDPE (1L) – KENODIN SD (formula 13)

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.28	5.56	5.57
Density	1.030	1.038	1.037
%iodine (%increase)	0.290 (-)	0.293 (+1.0)	0.304 (+4.8)

The products tested are considered stable at 5°C. However, the tests should be performed at 0°C to negate the need of the a storage restriction for low temperatures. The storage

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
conditions require the restriction 'Protect from frost'				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 4.1 (pure) (no range, because only one formula in this meta SPC)	See shelf-life data	Storage stability tests of meta SPC 4, Cirlam Laboratory, 3.4.1/1.4
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 4, Cirlam Laboratory, 3.4.1/1.4
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties /

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size	/	/	Not relevant	Guidance on

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
distribution, content of dust/fines, attrition, friability			because the product is a liquid.	the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor doesn't need to be diluted with water.	/
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness —	/	/	Not relevant because there	Guidance on the BPR,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
smoke generators			is no generation of smoke when using the products as described on the labels	Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in	CID LINES

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			combination with other products.	
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water.	CID LINES
Surface tension	OECD115	/	Kenodin SD has a surface tension of 30.98 mN/m at 20°C at 100% v/v.	ENSCL study report 07.05.2018.
Viscosity	OECD 114 (rotational viscometer)	Kenodin SD	At 20°C 16 mPa.s At 40°C 14 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

Meta SPC 5

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 5.1	liquid	Iodine Dip PVP – analysis, [redacted], 2015, 5/1.5.1
	Visual	The test substance is the formulation of SPC 1.5.2	liquid	Iodine SD PVP – analysis, [redacted], 2015, 5/1.5.2
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 5.1	Dark brown	Iodine Dip PVP – analysis, [redacted], 2015, 5/1.5.1
	Visual	The test substance is the formulation of SPC 5.2	Dark brown	Iodine SD PVP – analysis, [redacted], 2015, 5/1.5.2
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 5.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 5.2	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 5.1	5.41 at 20.5°C	Iodine Dip PVP – analysis, [redacted], 2015, 5/1.5.1
	CIPAC MT 75.3	The test substance is the formulation of SPC 5.2	5.45 at 22.5°C	Iodine SD PVP – analysis, [redacted], 2015, 5/1.5.2
	OECD 122	The test substance is the formulation F18 (max/max) of metaSPC 5	0.48 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F20 (max/min) of metaSPC 5	0.11 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	F18 Batch 5118120002 F20 Batch 5118120003	0.48% H_2SO_4 0.11% H_2SO_4	[redacted], 2019
eCA remark The reported values for the pH are specifications, rather than actual measured values. The				

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
actual measurements were: 5.41 at 20.5°C and 4.45 at 22.5°C respectively.				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 5.1	1.045 g/cm³ at 20.5°C	Iodine Dip PVP – analysis, [redacted], 2015, 5/1.5.1
	OECD Test guideline 109	The test substance is the formulation of SPC 5.2	1.048 g/cm³ at 20.0°C	Iodine SD PVP – analysis, [redacted], 2015, 5/1.5.2
eCA remark The reported (relative) density is a specification, rather than an actual measured value. The actual measurements were: 1.045 g/cm³ at 20.5°C and 1.048 g/cm³ at 20.0°C respectively.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 5.1, 5.2 (pure) and the combination minimum and maximum excipients (4 studies)	See summary by eCA below.	Storage stability tests of meta SPC 5, Cirlam Laboratory, 3.4.1/1.5

eCA remark
For meta SPC 5, the following accelerated data is available:

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F18

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.94	2.77	2.61
Density	1.049	1.048	1.048
Viscosity (mPa.s)	1680	1624	1600
%iodine (%increase)	0.331 (-)	0.313 (-5.4)	0.301 (-9.1)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F20

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.13	2.41	2.11
Density	1.008	1.008	1.0008
%iodine (%increase)	0.323 (-)	0.318 (-1.5)	0.312 (-3.4)

Storage at 40°C for 8 weeks in HDPE (1L) – Iodo PVP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.15	2.77	2.67
Density	1.033	1.032	1.034
Viscosity (mPa.s)	2320	1720	1530

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

%iodine (%increase)	0.345 (-)	0.321 (-7.0)	0.312 (-9.6)

Storage at 40°C for 8 weeks in HDPE (1L) – Iodo SD PVP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.83	2.70	2.69
Density	1.032	1.031	1.033
%iodine (%increase)	0.344 (-)	0.329 (-4.4)	0.320 (-7.0)

The formulations within meta SPC5 are considered stable under accelerated conditions as the active substance decrease does not exceed 10%.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 5.1, 5.2 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 5, Cirlam Laboratory, 3.4.1/1.4

eCA remark

The following shelf-life data is available for meta SPC5 (24m data is not yet available):

Storage at 25°C for 2 years in HDPE (1L) – Formula F18

	Initial	3 months	6 months	9 months	12 months	18 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.94	2.81	2.72	2.74	2.75	2.74
Density	1.049	1.050	1.051	1.050	1.051	1.050
Viscosity (mPa.s)	1680	1644	1608	1550	1566	1504
%iodine (%increase)	0.331 (-)	0.322 (-2.7)	0.313 (-5.7)	0.307 (-7.3)	0.303 (-8.5)	0.298 (-9.97)

Storage at 25°C for 2 years in HDPE (1L) – Formula F20

	Initial	3 months	6 months	9 months	12 months	18 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.13	2.03	2.16	2.13	2.01	2.28

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Density	1.008	1.009	1.009	1.009	1.008	1.009
%iodine (%increase)	0.323 (-)	0.308 (-4.6)	0.302 (-6.5)	0.296 (-8.4)	0.297 (-8.1)	0.291 (-9.9)

Storage at 25°C for 2 years in HDPE (1L) – Iodo PVP

	Initial	3 months	6 months	9 months	12 months	18 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.15	3.03	2.88	2.87	2.65	2.58
Density	1.033	1.034	1.032	1.033	1.032	1.032
Viscosity (mPa.s)	2320	2150	2030	1840	1620	1590
%iodine (%increase)	0.345 (-)	0.328 (-4.9)	0.320 (-7.3)	0.314 (-9.0)	0.314 (-9.0)	0.311 (-9.9)

Storage at 25°C for 2 years in HDPE (1L) – Iodo SD PVP

	Initial	3 months	6 months	9 months	12 months	18 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.83	2.81	2.65	2.70	2.60	2.56
Density	1.032	1.032	1.030	1.031	1.030	1.031
%iodine (%increase)	0.344 (-)	0.338 (-1.7)	0.332 (-3.5)	0.328 (-4.7)	0.323 (-6.1)	0.321 (-6.7)

Based on the interim 18 month data, the active substance decrease remained below 10%. At the same time, the accelerated data suggests the products are stable for 2 years. The eCA considers that a 2 year shelf-life should be considered supported, but it should be noted that it is likely the final data will need to be confirmed with efficacy data. Therefore, the applicant has proposed a shelf-life of 18 months for this meta SPC and has discontinued the ongoing studies.

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 5.1, 5.2 (pure) and the combination minimum and maximum excipients (4 studies)		Storage stability tests of meta SPC 5, Cirlam Laboratory, 3.4.1/1.5

eCA remark

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F18

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.94	2.98	2.84
Density	1.049	1.052	1.052

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Viscosity (mPa.s)	1680	1660	2440
%iodine (%increase)	0.331 (-)	0.332 (+0.3)	0.333 (+0.6)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F20

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.13	2.39	2.15
Density	1.008	1.008	1.009
%iodine (%increase)	0.323 (-)	0.321 (-0.6)	0.339 (+5.0)

Storage at 5°C for 8 weeks in HDPE (1L) – Iodo PVP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.15	3.09	3.12
Density	1.033	1.031	1.034
Viscosity (mPa.s)	2320	2150	2080
%iodine (%increase)	0.345 (-)	0.343 (-0.6)	0.336 (-2.6)

Storage at 5°C for 8 weeks in HDPE (1L) – Iodo SD PVP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.83	2.81	2.85
Density	1.032	1.031	1.033
%iodine (%increase)	0.344 (-)	0.345 (-0.3)	0.342 (-0.6)

The products tested are considered stable at 5°C. Considering a study at 0 °C should be conducted, a storage restriction is required: Protect from frost.

Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product –	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 5.1, 5.2 (pure) and the combination	See shelf-life data.	Storage stability tests of meta SPC 5, Cirlam Laboratory,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature and humidity		minimum and maximum excipients (4 studies)		3.4.1/1.5
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 5, Cirlam Laboratory, 3.4.1/1.5
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			and therefor doesn't need to be diluted with water.	
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when	Guidance on the BPR, Volume I: Identity/physico-chemical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			using the products as described on the labels	properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water.	CID LINES
Surface tension	OECD115	/	Iodo SD PVP has a surface tension of 30.60 mN/m at 20°C at 100% v/v.	ENSCL study report 07.05.2018.
Viscosity	OECD Test guideline 114	The test substance is the formulation of SPC 5.1	1500-6000 cP	Iodine Dip PVP – analysis, Chenu, J.,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				2015, 5/1.5.1
	OECD 114 (rotational viscometer)	F20 Batch 5118500005 F18 Batch 5116510005	At 20°C <10 mPa.s At 40°C <10 mPa.s At 20°C 1680 mPa.s At 40°C 400 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 6

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 6.1	liquid	Dermades PVP – analysis, [redacted], 2015, 5/1.6.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 6.1	Dark brown	Dermades PVP – analysis, [redacted], 2015, 5/1.6.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 6.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 6.1	5.33 at 22.5°C	Dermades PVP – analysis, [redacted], 2015, 5/1.6.1
eCA remark The value reported is a specification rather than an actual measurement. The value determined is 5.33 at 22.5°C.				
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 6.1	1.085 g/cm³ at 21.0°C	Dermades PVP – analysis, [redacted], 2015, 5/1.6.1
eCA remark The value reported is a specification rather than an actual measurement. The value determined is 1.085g/cm³ at 21.0°C.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 6.1 (pure) (no range, because only one formula in this meta SPC)	See summary by eCA below.	Storage stability tests of meta SPC 6, Cirlam Laboratory, 3.4.1/1.6
eCA remark The following accelerated data was provided, showing the product is stable for 8 weeks at 40°C in HDPE: Storage at 40°C for 8 weeks in HDPE (1L) – Dermades PVP				

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.42	5.17	5.07

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Density	1.084	1.083	1.084
%iodine (%increase)	0.968 (-)	0.900 (-7.0)	0.895 (-7.5)

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 6.1 (pure) (no range, because only one formula in this meta SPC)	See summary by eCA below.	Storage stability tests of meta SPC 6, Cirlam Laboratory, 3.4.1/1.6

eCA remark
The final shelf-life study was provided, showing the product is stable for 2 years in HDPE:

Storage at 25°C for 2 years in HDPE (1L) – Dermades PVP

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.42	5.22	5.24	5.11	5.10	5.05	5.10
Density	1.084	1.084	1.084	1.085	1.085	1.083	1.084
%iodine (%increase)	0.968 (-)	0.976 (+0.8)	0.980 (+1.2)	0.929 (-4.0)	0.911 (-5.9)	0.908 (-6.2)	0.912 (-5.8)

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 6.1 (pure) (no range, because only one formula in this meta SPC)	See summary below	Storage stability tests of meta SPC 6, Cirlam Laboratory, 3.4.1/1.6

eCA remark

Storage at 5°C for 8 weeks in HDPE (1L) – Dermades PVP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.42	5.29	5.26
Density	1.084	1.084	1.085
%iodine (%increase)	0.968 (-)	0.986 (+1.9)	0.996 (+2.9)

The products tested are considered stable at 5°C. Considering the study should be performed at 0°C, a storage restriction is required: Protect from frost.

Effects on content of the active substance and technical characteristics of the biocidal product -	/	/	Not relevant as the commercial packagings are not transparent.	CID LINES

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
light			Moreover stability tests have been done in the commercial packaging	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 6.1 (pure) (no range, because only one formula in this meta SPC)	See shelf-life data.	Storage stability tests of meta SPC 6, Cirlam Laboratory, 3.4.1/1.6
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 6, Cirlam Laboratory, 3.4.1/1.6
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor doesn't need to be diluted with water.	/
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology –

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the labels	part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should	CID LINES

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			not be diluted with water.	
Surface tension	OECD 115	/	Dermades PVP has a surface tension of 29.82 mN/m at 20°C at 100% v/v.	ENSCL study report 07.05.2018
Viscosity	OECD 114 (rotational viscometer)	Dermades PVP Batch 5118500007	At 20°C 37 mPa.s At 40°C 25 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 7

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 7.1	liquid	Iodine – analysis, [redacted], 2015, 5/1.7.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 7.1	Dark brown	Iodine – analysis, [redacted], 2015, 5/1.7.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 7.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 7.1	2.65 at 21°C	Iodine – analysis, [redacted], 2015, 5/1.7.1
	OECD 122	The test substance is the formulation F25 (min/min) of metaSPC 7	0.24 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F26 (max/max) of metaSPC 7	0.39 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F27 (min/max) of metaSPC 7	0.37 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F28 (max/max) of metaSPC 7	0.45 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	F25 Batch S511701 F26 Batch S511705 F27 Batch S511815 F28	0.24% H_2SO_4 0.39% H_2SO_4 0.37% H_2SO_4 0.45% H_2SO_4	[redacted], 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		5116520012		

eCA remark
The value reported is a specification rather than an actual measurement. The representative product's pH is 2.65 at 21°C according to the test report.

The acidity of the representative product was not tested. However, the applicant has provided data on four model formulations. The acidity of the representative product will be in the same order of magnitude.

Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 7.1	1.033 at 20.5°C	Iodine – analysis, [redacted], 2015, 5/1.7.1
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 7.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 7, Cirlam Laboratory, 3.4.1/1.7

eCA remark

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F25

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.54	2.45	2.52
Density	1.019	1.019	1.018
%iodine (%increase)	1.022 (-)	0.947 (-7.3)	0.936 (-8.4)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F26

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.64	2.46	2.47
Density	1.062	1.060	1.060
%iodine (%increase)	3.080 (-)	3.029 (-1.7)	3.012 (-2.2)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F27

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.71	2.69	2.69
Density	1.046	1.044	1.044

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
%iodine (%increase)	1.088 (-)	1.017 (-6.5)	1.077 (-1.0)	

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F28

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.18	3.15	3.20
Density	1.050	1.048	1.047
%iodine (%increase)	3.266 (-)	3.489 (+6.8)	3.171 (-2.9)

Storage at 40°C for 8 weeks in HDPE (1L) – Dodin 20

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.69	2.55	2.42
Density	1.032	1.032	1.033
%iodine (%increase)	1.821 (-)	1.733 (-4.8)	1.765 (-3.1)

During storage, the iodine content remains within 10% of the initial content.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 7.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 7, Cirlam Laboratory, 3.4.1/1.7

eCA remark

For the representative product and the model formulations representing meta SPC 7, shelf-life data is available, showing all potential products in the meta SPC should be stable for at least 2 years when stored at ambient conditions, in HDPE packaging.

Storage at 25°C for 2 years in HDPE (1L) – Formula F25

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.54	2.60	2.43	2.60	2.51	2.44	2.38
Density	1.019	1.018	1.019	1.019	1.019	1.020	1.019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

%iodine (%increase)	1.022 (-)	0.998	0.986	0.966	0.958	0.938	0.925 (-9.5)

Storage at 25°C for 2 years in HDPE (1L) – Formula F26

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.64	2.60	2.52	2.58	2.44	2.35	2.29
Density	1.062	1.059	1.060	1.062	1.060	1.063	1.061
%iodine (%increase)	3.080 (-)	3.056 (-0.8)	3.051 (-0.9)	2.996 (-2.7)	3.006 (-2.4)	2.995 (-2.8)	2.965 (-3.7)

Storage at 25°C for 2 years in HDPE (1L) – Formula F27

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.71	2.67	2.86	2.69	2.72	2.76	2.74
Density	1.046	1.044	1.046	1.047	1.045	1.047	1.045
%iodine (%increase)	1.088 (-)	1.078 (-0.9)	1.080 (-0.7)	1.091 (+0.3)	1.076 (-1.1)	1.088 (-)	1.089 (+0.1)

Storage at 25°C for 2 years in HDPE (1L) – Formula F28

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.18	2.80	3.14	3.25	3.29	3.37	3.43
Density	1.050	1.047	1.044	1.047	1.047	1.047	1.047
%iodine (%increase)	3.266 (-)	3.244 (-0.7)	3.182 (-2.6)	3.193 (-2.2)	3.307 (+1.3)	3.199 (-2.1)	3.306 (+1.2)

Storage at 25°C for 2 years in HDPE (1L) – Dodin 20

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.69	2.57	2.56	2.50	2.34	2.40	2.56
Density	1.032	1.027	1.033	1.033	1.033	1.034	1.033
%iodine (%increase)	1.821 (-)	1.739 (-4.5)	1.712 (-6.0)	1.729 (-5.1)	1.741 (-4.4)	1.702 (-6.5)	1.699 (-6.7)

For the dilution stability, please refer to the respective entry below (separate study).

Storage stability test	Guidance on	The test substance	See summary	Storage

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
– **low temperature stability test for liquids**	the Biocidal Products Regulation	is the formulation of SPC7.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	by eCA below.	stability tests of meta SPC 7, Cirlam Laboratory, 3.4.1/1.7

eCA remark
The following data was submitted to support the low temperature stability of meta SPC 7:

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F25

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.54	2.51	2.60
Density	1.019	1.019	1.019
%iodine (%increase)	1.022 (-)	0.978 (-4.3)	0.975 (-4.6)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F26

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.64	2.68	2.70
Density	1.062	1.060	1.061
%iodine (%increase)	3.080 (-)	3.061 (-0.6)	3.060 (-0.6)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F27

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.71	2.71	2.74
Density	1.046	1.025	1.044
%iodine (%increase)	1.088 (-)	1.083 (-0.5)	1.086 (-0.2)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F28

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	3.18	2.75	2.72
Density	1.050	1.048	1.050
%iodine (%increase)	3.266	3.514	3.341

Storage at 5°C for 8 weeks in HDPE (1L) – Dodin 20

	Initial	4w	8w

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	
pH	2.69	2.67	2.53	
Density	1.032	1.034	1.033	
%iodine (%increase)	1.821 (-)	1.721 (-5.5)	1.770 (-2.8)	
The products tested are considered stable at 5°C. Considering a study should be conducted at 0°C, a storage restriction is required: Protect from frost.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 7.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 7, Cirlam Laboratory, 3.4.1/1.7
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 7, Cirlam Laboratory, 3.4.1/1.7
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	CIPAC MT 47.2	The test substance is the formulation of meta SPC 7 (maximum active substance, maximum of all excipients)	According to the results of the foam test performed according to CIPAC MT 47.2 method, MetaSPC 7 presents a remaining quantity of foam of 36 mL after 60 seconds.	Antczak, 2015
eCA remark 2.66 mL of model formulation 26 was used (1.33%v/v) in CIPAC C water. This formulation represents the highest surfactant concentration within the meta SPC.				
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	CIPAC MT 41	The test substance is the formulation F26 at the maximum in-use concentration (1.2%)	The tested product forms a stable aqueous dilution	Dilution test of BPF Iodine according to CIPAC MT 41, Platteau, J., 2018, 3.4.1/1.1
	CIPAC MT41	Meta SCP1: KENODIN SD 400 Batch 5117100012 Meta SCP7: F26 Batch S511705 Meta SCP8: F30 Batch S511805 Meta SCP9: F55 Batch S512507 Meta SCP10:	All tested formulation formed stable dilutions, leaving no residue on a 75µm sieve after 24 hours in CIPAC D water. Tested concentrations: 20% KENODIN SD 400 1.2% F26 1% F30 and	Platteau, J, 2019 and 2019a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		KENODIN SD 900 Batch 5117420012 24m aged samples: Iodo 20 Batch 0061718118 Kenodin SD900 Batch 0041718091	F55 11% KENODIN SD 900.	
eCA remark The products tested represent the following meta SPCs:KENODIN SD 400: meta SPC 1, a ready to use product. Meta SPC 8 and 9 are represented by model formulations F26, F30 and F55 respectively, with the maximum iodine content specified and the maximum co-formulants concentrations. Generally, with exception of iodine itself, the co-formulants within the family are readily water soluble, but using the highest concentrations of co-formulants may not necessary be worst-case as the surfactants used to complexate iodine are also present at their highest concentrations. This means the worst-case is not covered, but judging the representative products, combining the maximum iodine concentration with the lowest surfactant concentration is not a reasonable option as the ratio between surfactants and iodine are more or less fixed. Meta SPCs 7 – 10 are all based on iodophor 1 (surfactant stabilised iodine). For meta SPC10 this is not an issue as it the composition is not flexible. The ratio for meta SPC 8 is identical to that of meta SPC 10, which supports the assumption that there is sufficient surfactant present to keep iodine in solution. For meta 7 and 9 the relative amount of surfactant in the representative products, compared to iodine, is higher than that for meta SPCs 8 and 10. Therefore, meta SPC 7 and 9 are expected to be more worst-case. KENODIN SD 900: meta SPC 10. The aged products tested, for which no t=0 is available as the tests were not part of the shelf-life study, also formed stable dilutions (Iodo 20 representing meta SPC 7 and KENODIN SD900 representing meta SPC 10).				
Surface tension	OECD 115	/	Dodin 20 has a surface tension of 29.05 mN/m at 20°C at 1.2% v/v dilution.	ENSCL study report 07.05.2018
Viscosity	OECD 114 (rotational viscometer)	F25 Batch 5118500008 F26 Batch 5118500009	At 20°C 17 mPa.s At 40°C 37 mPa.s At 20°C 158 mPa.s At 40°C	Platteau, J., 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			53 mPa.s Shear rate not indicated.	
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 8

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 8.1	liquid	Iocid 30 – analysis, [redacted], 2015, 5/1.8.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 8.1	Dark brown	Iocid 30 – analysis, [redacted], 2015, 5/1.8.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 8.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 8.1	1.18 at 22.0°C	Iocid 30 – analysis, [redacted], 2015, 5/1.8.1
	OECD 122	The test substance is the formulation F29 (min/min) of metaSPC 8	3.17 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F30 (max/max) of metaSPC 8	9.80 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F31 (min/max) of metaSPC 8	9.54 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F32 (max/min) of metaSPC 8	4.15 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	F29 Batch S511711 F30 Batch S511805 F31 Batch S512607 F32	3.17% H_2SO_4 9.80% H_2SO_4 9.54% H_2SO_4 4.15% H_2SO_4	[redacted], 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch S512705		

eCA remark
The reported pH is a specification rather than an actual measured value. The pH of the representative product (Iocid 30) is 2.65 at 21°C, which is outside the specification. The report describes the test item as 'Iodine'. It is therefore unknown whether the study was performed with the correct product. The other data submitted for this product all report pH values in the specification range. Therefore, the eCA assumes the data is not reliable and the pH as reported in the stability studies should be used (initial pH 0.94).

The acidity data was generated using model formulations. The representative product is expected to have an acidity in the same order of magnitude.

Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 8.1	1.100 at 20.0°C	Iocid 30 – analysis, [redacted], 2015, 5/1.8.1
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 8.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 8, Cirlam Laboratory, 3.4.1/1.8

eCA remark

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F29

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.35	1.24	1.31
Density	1.038	1.038	1.037
%iodine (%increase)	1.003 (-)	0.979 (-2.4)	0.962 (-4.1)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F30

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.05	1.04	1.08
Density	1.127	1.126	1.125
%iodine (%increase)	3.073 (-)	3.025 (-1.6)	3.049 (-0.8)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F31

	Initial	4w	8w

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.88	1.00	0.67
Density	1.101	1.102	1.101
%iodine (%increase)	0.987 (-)	1.047 (+6.1)	1.063 (+7.7)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F32

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.30	1.30	1.32
Density	1.064	1.058	1.059
%iodine (%increase)	3.656 (-)	3.628 (-0.8)	3.334 (-8.8)

Storage at 40°C for 8 weeks in HDPE (1L) – Iocid 30

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.94	0.86	1.12
Density	1.121	1.120	1.122
%iodine (%increase)	3.056 (-)	3.158 (+3.3)	3.117 (+2.0)

Iodine levels remain within 10% of the initial content for all formulations tested.

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 1.8.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 8, Cirlam Laboratory, 3.4.1/1.8

eCA remark

The following shelf-life data was provided, showing all formulations within the meta SPC may be expected to be stable for 2 years at ambient conditions.

Storage at 25°C for 2 years in HDPE (1L) – Formula F29

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.35	1.44	1.47	1.47	1.19	1.35	1.35
Density	1.038	1.037	1.038	1.039	1.038	1.039	1.038

Property	Guideline and Method	Purity of the test substance (% (w/w)		Results		Reference	
%iodine (%increase)	1.003 (-)	0.991 (-1.2)	0.975 (-2.8)	0.939 (-6.4)	0.963 (-4.0)	0.949 (-5.4)	0.933 (-7.0)

Storage at 25°C for 2 years in HDPE (1L) – Formula F30

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.05	1.13	1.17	1.19	0.93	0.98	0.97
Density	1.127	1.124	1.125	1.127	1.125	1.125	1.125
%iodine (%increase)	3.073 (-)	3.042 (-1.0)	3.022 (-1.7)	2.999 (-2.4)	2.978 (-3.1)	2.993 (-2.6)	2.999 (-2.4)

Storage at 25°C for 2 years in HDPE (1L) – Formula F31

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.88	0.90	0.75	0.77	0.80	0.79	0.93
Density	1.101	1.101	1.115	1.101	1.103	1.102	1.103
%iodine (%increase)	0.987 (-)	1.047 (+6.1)	1.075 (+8.9)	1.085 (+9.9)	1.080 (+9.4)	1.083 (+9.7)	1.082 (+9.6)

Storage at 25°C for 2 years in HDPE (1L) – Formula F32

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.30	1.33	1.17	1.19	1.18	1.20	1.19
Density	1.064	1.064	1.053	1.050	1.061	1.047	1.065
%iodine (%increase)	3.656 (-)	3.495 (-4.4)	3.476 (-4.9)	3.378 (-7.6)	3.377 (-7.6)	3.323 (-9.1)	3.297 (-9.8)

Storage at 25°C for 2 years in HDPE (1L) – Iocid 30

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.94	1.21	0.96	1.07	1.29	0.88	0.77
Density	1.121	1.121	1.120	1.120	1.121	1.121	1.122
%iodine (%increase)	3.056 (-)	3.074 (+0.6)	3.037 (-0.6)	3.040 (-0.5)	3.039 (-0.6)	3.032 (-0.8)	3.048 (-0.3)

Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 1.8.1, (pure) and the	See summary by eCA below.	Storage stability tests of meta SPC 8, Cirlam

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.		Laboratory, 3.4.1/1.8

eCA remark

The following low temperature stability data was made available:

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F29

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.35	1.27	1.30
Density	1.038	1.037	1.039
%iodine (%increase)	1.003 (-)	1.004 (+0.1)	1.006 (+0.3)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F30

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.05	1.02	1.07
Density	1.127	1.125	1.125
%iodine (%increase)	3.073 (-)	3.046 (-0.9)	3.052 (-0.7)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F31

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.88	1.00	0.81
Density	1.101	1.101	1.101
%iodine (%increase)	0.987 (-)	1.016 (+2.9)	1.027 (+4.1)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F32

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.30	1.29	1.31
Density	1.064	1.057	1.059
%iodine (%increase)	3.656 (-)	3.651 (-0.1)	3.591 (-1.8)

Storage at 5°C for 8 weeks in HDPE (1L) – Iocid 30

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	0.94	0.82	0.97
Density	1.121	1.123	1.122

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
%iodine (%increase)	3.056 (-)	3.145 (+2.9)	3.066 (+0.3)	
The products tested are considered stable at 5°C. Considering a study should be performed at 0°C, a storage restriction is required: Protect from frost.				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 1.8.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See shelf-life dataF31 (min, max), F32 (max, min)	Storage stability tests of meta SPC 8, Cirlam Laboratory, 3.4.1/1.8
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 8, Cirlam Laboratory, 3.4.1/1.8
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physic

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				o-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	CIPAC MT 47.2	The test substance is the formulation of meta SPC 8 (maximum active substance, maximum of all excipients)	According to the results of the foam test performed according to CIPAC MT 47.2 method, MetaSPC 8 presents a remaining quantity of foam of 34 mL after 60 seconds.	Antczak, S, 2015
eCA remark The test was performed using 2.66mL formula 30 (model formulation with maximum surfactant concentration) in 200mL CIPAC water C (~1.33%v/v). 34 mL foam persisted after 1 minute, which is acceptable.				
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology –

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are	Guidance on the BPR, Volume I:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			not aerosol	Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	CIPAC MT 41	The test substance is the formulation F30 at the maximum in-use concentration (1%)	The tested product forms a stable aqueous dilution	Dilution test of BPF Iodine according to CIPAC MT 41, Platteau, J., 2018, 3.4.1/1.1
eCA remark TIn the original shelf-life studies, the dilution stability was not tested after storage. Some tests were re-done and aged samples were tested. The outcome of the studies is reported under meta SPC 7 (Platteau, 2019 and 2019a), including a justification for read-across between the meta SPCs with SL formulations (meta SPC 7 – 10).				
Surface tension	OECD 115	/	Iocid 30 has a surface tension of 30.63 mN/m at 20°C at 1% v/v dilution.	ENSCL study report 07.05.2018
Viscosity	OECD 114 (rotational viscometer)	F29 Batch 5118500002 F30 Batch 5118500003	At 20°C 26 mPa.s At 40°C 19 mPa.s At 20°C 286 mPa.s At 40°C	Platteau, J., 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			64 mPa.s Shear rate not indicated.	
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

MetaSPC 9

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 9.1	liquid	Iodo CIP – analysis, [redacted], 2015, 5/1.9.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 9.1	Dark brown	Iodo CIP – analysis, [redacted], 2015, 5/1.9.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 9.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 9.1 (1% dilution)	2.0 at 24°C	Iodo CIP – analysis, [redacted], 2015, 5/1.9.1
	OECD 122	The test substance is the formulation F53 (min/min) of metaSPC 9	8.06 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F54 (max/min) of metaSPC 9	8.30 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F55 (max/max) of metaSPC 9	23.68 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	The test substance is the formulation F56 (min/max) of metaSPC 9	24.94 m/m% H_2SO_4	Acidity test report: BPF iodine formulations, [redacted], 2018, 3.2
	OECD 122	F53 Batch 5118120004 F54 Batch 5118120005 F55 Batch 5118120006 F56	8.06% H_2SO_4 8.30% H_2SO_4 23.68% H_2SO_4 24.94% H_2SO_4	[redacted], 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Batch 511812007		

eCA remark
The reported pH is a specification, rather than an actual measurement. The measured pH of the representative formulation for meta SPC 9 is 2.0 at 24°C.

The acidity data was generated using four model formulations. The pH of the products within the meta SPC are expected to be in the same order of magnitude.

Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 9.1	1.140-1.180	Iodo CIP – analysis, [redacted], 2015, 5/1.9.1
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 9.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 9, Cirlam Laboratory, 3.4.1/1.9

eCA remark
Products within the meta SPC are not stable, showing decreases in iodine content of up to 14.3% during the storage trials. Efficacy data is required to show the products are still efficacious after storage. The applicant proposed to not store the products at or above 40°C. The product is not stable at this temperature, however. The applicant should therefore propose more adequate storage conditions, supported by appropriate data.

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F53

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.95	1.82	1.82
Density	1.188	1.188	1.189
%iodine (%increase)	0.496 (-)	0.430 (-13.3)	0.424 (-14.5)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F54

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	2.06	2.06
Density	1.156	1.154	1.155
%iodine (%increase)	0.945 (-)	0.879 (-7.0)	0.924 (-2.2)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F55

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.83	1.67	1.93
Density	1.206	1.205	1.205
%iodine (%increase)	0.949 (-)	0.895 (-5.7)	0.876 (-7.7)

Storage at 40°C for 8 weeks in HDPE (1L) – Formula F56

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	1.92	1.82
Density	1.124	1.123	1.123
%iodine (%increase)	0.478 (-)	0.442 (-7.5)	0.434 (-9.2)

Storage at 40°C for 8 weeks in HDPE (1L) – Iodo CIP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.65	1.79	1.95
Density	1.164	1.163	1.167
%iodine (%increase)	0.504 (-)	0.477 (-5.4)	0.432 (-14.3)

Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 1.9.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 9, Cirlam Laboratory, 3.4.1/1.9

eCA remark

The following shelf-life data is available in HDPE, showing the products are generally stable at ambient conditions.

It should be noted that the dilution stability after storage was not addressed.

Storage at 25°C for 2 years in HDPE (1L) – Formula F53

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.95	1.68	1.77	1.92	1.96	1.85	1.91
Density	1.188	1.189	1.191	1.190	1.190	1.190	1.190

Property	Guideline and Method	Purity of the test substance (% (w/w)		Results		Reference	
%iodine (%increase)	0.496 (-)	0.477 (-3.8)	0.473 (-4.6)	0.468 (-5.7)	0.464 (-6.5)	0.456 (-8.1)	0.455 (-8.3)

Storage at 25°C for 2 years in HDPE (1L) – Formula F54

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	1.77	1.85	1.97	1.99	2.02	1.99
Density	1.156	1.157	1.156	1.156	1.157	1.155	1.157
%iodine (%increase)	0.945 (-)	0.883 (-6.6)	0.873 (-7.6)	0.876 (-7.3)	0.857 (-9.3)	0.859 (-9.1)	0.852 (-9.8)

Storage at 25°C for 2 years in HDPE (1L) – Formula F55

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.83	1.91	1.56	1.89	1.88	2.07	1.90
Density	1.206	1.204	1.203	1.205	1.206	1.204	1.205
%iodine (%increase)	0.949 (-)	0.916 (-3.5)	0.892 (-6.0)	0.877 (-7.6)	0.883 (-7.0)	0.859 (-9.5)	0.862 (-9.2)

Storage at 25°C for 2 years in HDPE (1L) – Formula F56

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	1.80	1.79	2.03	1.98	2.25	1.75
Density	1.124	1.123	1.123	1.123	1.125	1.122	1.123
%iodine (%increase)	0.478 (-)	0.437 (-8.6)	0.443 (-7.3)	0.436 (-8.8)	0.430 (-10.0)	0.432 (-9.6)	0.430 (-10.0)

Storage at 25°C for 2 years in HDPE (1L) – Iodo CIP

	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.65	1.68	1.82	1.87	1.82	1.83	1.83
Density	1.164	1.164	1.166	1.165	1.165	1.165	1.164
%iodine (%increase)	0.504 (-)	0.453 (-10.1)	0.476 (-5.6)	0.468 (-7.1)	0.464 (-7.9)	0.456 (-9.5)	0.462 (-8.3)

Iodo CIP shows a decrease of slightly above 10% after 3 months. In addition, the values rounded to 10.0 for model formulation 56 also slightly exceed the 10% threshold. This decrease was addressed using efficacy data. See the confidential annex (paragraph 3.4)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
for details on details on tested formulations and concentrations. Assessment of breakdown products is not considered necessary. The primary breakdown products is iodide and the molecule oxidised in the process would be impossible to identify. In addition, no negative impact on risks for the user are expected.				
Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 9.1, (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See summary by eCA below.	Storage stability tests of meta SPC 9, Cirlam Laboratory, 3.4.1/1.9

eCA remark
The following low temperature stability data is available:

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F53

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.95	1.86	1.91
Density	1.188	1.190	1.188
%iodine (%increase)	0.496 (-)	0.449 (-9.5)	0.443 (-10.7)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F54

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	2.03	2.00
Density	1.156	1.156	1.155
%iodine (%increase)	0.945 (-)	0.970 (+2.7)	0.870 (-7.9)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F55

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.83	1.70	1.97
Density	1.206	1.205	1.205
%iodine (%increase)	0.949 (-)	0.928 (-2.2)	0.951 (+0.2)

Storage at 5°C for 8 weeks in HDPE (1L) – Formula F56

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	2.01	1.96	1.88

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Density	1.124	1.124	1.124	
%iodine (%increase)	0.478 (-)	0.463 (-3.1)	0.443 (-7.3)	

Storage at 5°C for 8 weeks in HDPE (1L) – Iodo CIP

	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	1.65	1.85	1.92
Density	1.164	1.164	1.165
%iodine (%increase)	0.504 (-)	0.441 (-12.5)	0.469 (-6.9)

The storage data show a possible degradation of >10% occurs. As this is a low temperature study, it is not possible to use storage restrictions to address this.

It is noted that the degradation at 5°C exceeds that found in the real-time studies, which is normally not expected, especially considering this meta SPC does not contain stabilisers or a redox agent. It is therefore also surprising to see that there is no clear trend in the active substance contents: in some cases the iodine concentration is first raised, then lowered and vice versa, compared to the intial concentration. This should not be caused by analytical error alone. It may have been caused by the experimental setup, however.

As there is no clear reason for the observations. the eCA considers that efficacy testing is necessary to show that products within this meta SPC are still efficacious after storage. Some products showed a decrease in active substance content of >10%. See the confidential annex (paragraph 3.4) for details on details on tested formulations and concentrations. Degradation up to 14.5% is covered.

To address the issues observed, the applicant has proposed to include a storage restriction "Protect from frost". In addition, efficacy studies show there is no reason for concern.

Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 9.1, (pure) and the combination min active	See shelf-life data	Storage stability tests of meta SPC 9, Cirlam Laboratory, 3.4.1/1.9

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
humidity		substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.		
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 9, Cirlam Laboratory, 3.4.1/1.9
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming	CIPAC MT 47.2	The test substance is the formulation of meta SPC 9 (maximum active substance, maximum of all excipients)	According to the results of the foam test performed according to CIPAC MT 47.2 method, MetaSPC 9 presents a remaining quantity of foam of 10 mL after 60 seconds.	Degryse, J, 2015
eCA comment Model formulation 64 was used for the test, containing the maximum amount of surfactant for this meta SPC. 0.25mL of product was added to 200mL CIPAC C water (~0.13%). The amount of foam reported in the study is 2 mL after 60 seconds (in contrast to what is reported in the summary above).				
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no	Guidance on the BPR, Volume I:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			generation of smoke when using the products as described on the labels	Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination	CID LINES

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with other products.	
Degree of dissolution and dilution stability	CIPAC MT 41	The test substance is the formulation F55 at the maximum in-use concentration (1%)	The tested product forms a stable aqueous dilution	Dilution test of BPF Iodine according to CIPAC MT 41, Platteau, J., 2018, 3.4.1/1.1
eCA remark In the original shelf-life studies, the dilution stability was not tested after storage. Some tests were re-done and aged samples were tested. The outcome of the studies is reported under meta SPC 7 (Platteau, 2019 and 2019a), including a justification for read-across between the meta SPCs with SL formulations (meta SPC 7 – 10).				
Surface tension	OECD 115	/	Iodo CIP has a surface tension of 31.75 mN/m at 20°C at 1% v/v.	ENSCL study report 07.05.2018
Viscosity	OECD 114 (rotational viscometer)	F53 Batch 5118500003 F55 Batch 5118500004	At 20°C <10 mPa.s At 40°C <10 mPa.s At 20°C 26 mPa.s At 40°C 23 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 10.1 (pure)	liquid	Kenodin SD 900 – analysis, [redacted], 2015, 5/1.10.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation	Dark brown	Kenodin SD 900 – analysis,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		of SPC 10.1 (pure)		[redacted], 2015, 5/1.10.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 10.1 (pure)	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 10.1 (pure)	5.82 at 21.5°C	Kenodin SD 900 – analysis, [redacted], 2015, 5/1.10.1
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The value reported fort he pH is a specification, not an actual measurement. For KENODIN SD 900, the measured pH is 5.82 at 21.5°C. Acidity data is not considered required for this meta SPC.				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 10.1 (pure)	1.106 g/cm³ at 20.5°C	Kenodin SD 900 – analysis, [redacted], 2015, 5/1.10.1
eCA remark The value reported fort he density is a specification, not an actual measurement. The reported density of KENODIN SD 900 is 1.106 g/cm^3 at 20.5°C.				
Storage stability test – **accelerated storage**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 10.1 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See eCA summary	Storage stability tests of meta SPC 10, Cirlam Laboratory, 3.4.1/1.10
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 1 (original meta SPC 1 was split).				
Storage stability test – **long term storage at ambient temperature**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 10.1 (pure) and the combination min active	See eCA summary	Storage stability tests of meta SPC 10, Cirlam Laboratory, 3.4.1/1.10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.		
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 1 (original meta SPC 1 was split).				
Storage stability test – **low temperature stability test for liquids**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 10.1 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min active/max excipients and max active/max excipients.	See eCA summary	Storage stability tests of meta SPC 10, Cirlam Laboratory, 3.4.1/1.10
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 1 (original meta SPC 1 was split).				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging.	CID LINES
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Guidance on the Biocidal Products Regulation	The test substance is the formulation of SPC 10.1 (pure) and the combination min active substance/minimum excipients, max active/minimum excipients, min	See shelf-life data.	Storage stability tests of meta SPC 10, Cirlam Laboratory, 3.4.1/1.10

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		active/max excipients and max active/max excipients.		
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 10, Cirlam Laboratory, 3.4.1/1.10
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A:

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Information Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	CIPAC MT 47.2	The test substance is the Formula 2 with 3% Iodine and the maximum	According to the results of the foam test performed	Foam test of Formula 2 according to CIPAC MT 47.2,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		of all excipients in meta SPC 10	according to CIPAC MT 47.2 method, MetaSPC 1 presents a remaining quantity of foam of 42 mL after 60 seconds.	Antczak, S, 2015, 3.5/1.10
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 1 (original meta SPC 1 was split).				
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	CIPAC MT 41	The test substance is the formulation Kenodin SD 900 at the maximum in-use concentration	The tested product forms a stable aqueous dilution	Dilution test of BPF Iodine according to CIPAC MT 41, Platteau, J.,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		(11%)		2018, 3.4.1/1.1
eCA remark In the original shelf-life studies, the dilution stability was not tested after storage. Some tests were re-done and aged samples were tested. The outcome of the studies is reported under meta SPC 7 (Platteau, 2019 and 2019a), including a justification for read-across between the meta SPCs with SL formulations (meta SPC 7 – 10).				
Surface tension	OECD 115	/	Kenodin SD 900 has a surface tension of 29.98 mN/m at 20°C at 11% v/v dilution	ENSCL study report 07.05.2018
Viscosity	OECD 114 (rotational viscometer)	Kenodin SD 900 Batch 5118500012	At 20°C 636 mPa.s At 40°C 272 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

metaSPC 11

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 1.11.1	liquid	Kenodin 2500 – analysis, [redacted], 2015, 5/1.11.1
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 11.1	Dark brown	Kenodin 2500 – analysis, [redacted], 2015, 5/1.11.1
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 11.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 11.1	5.31 at 22.0°C	Kenodin 2500 – analysis, [redacted], 2015, 5/1.11.1
	OECD 122		No test according to OECD 122 has	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			been provided as the pH is between 4-10	
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 11.1	1.037 at 21°C	Kenodin 2500 – analysis, [redacted] 2015, 5/1.11.1
Storage stability test – **accelerated storage**	/	/	Please see the eCA summary below.	Storage stability tests of meta SPC 11, Cirlam Laboratory, 3.4.1/1.11
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 2 (original meta SPC 2 was split).				
Storage stability test – **long term storage at ambient temperature**	/	/	Please see the eCA summary below.	Storage stability tests of meta SPC 11, Cirlam Laboratory, 3.4.1/1.11
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 2 (original meta SPC 2 was split).				
Storage stability test – **low temperature stability test for liquids**	/	/	Please see the eCA summary below.	Storage stability tests of meta SPC 11, Cirlam Laboratory, 3.4.1/1.11
eCA remark Details on the representative product for this meta SPC is reported under meta SPC 2 (original meta SPC 2 was split).				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	/	/	Not relevant as the commercial packagings are not transparent. Moreover stability tests have been done in the commercial packaging	CID LINES
Effects on content of the active substance and technical characteristics of the	/	/	Please refer to the shelf-life data.	Storage stability tests of meta SPC 11, Cirlam

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
biocidal product – **temperature and humidity**				Laboratory, 3.4.1/1.11
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 11, Cirlam Laboratory, 3.4.1/1.11
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor	/

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			doesn't need to be diluted with water.	
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the	Guidance on the BPR, Volume I: Identity/physico-chemical properties /

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			products as described on the labels	analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water.	CID LINES
Surface tension	OECD115	/	In OECD115 it is clearly stated under 'initial considerations' that measurement of surface tension is restricted to aqueous	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			solutions with a dynamic viscosity of less than 200 mPa. Kenodin 2500 has a viscosity of 2370 cPa at 20.5°C so surface tension is not relevant for this product.	Requirements, version 1.1, ECHA, November 2014
Viscosity	OECD Test guideline 114	The test substance is the formulation of SPC 1.11.1	1500-6000 mPa.s	Kenodin 2500 – analysis, Chenu, J., 2015, 5/1.11.1
	OECD 114 (rotational viscometer)	Kenodin 2500 Batch 5118500013 F10 Batch 5118500004	At 20°C 1845 mPa.s At 40°C 1205 mPa.s At 20°C 76 mPa.s At 40°C 72 mPa.s Shear rate not indicated.	Platteau, J., 2019
eCA remark The applicant reasons surface tension data is not required considering the product's visocity. The eCA considers that the reasoning is acceptable. The ring method will become less accurate with increasing viscosity. Based on the composition of this meta SPC, the product is expected to be surface active as it contains a significant amount of surfactants. For the viscosity acceptable data is available. The shear rate of the viscosity determinations was not reported, which is a deficiency. Considering the composition of the products within the family, the viscosity is not critical to the assessment as consideration for classification as an aspiration hazard (H304) is not necessary.				

Meta SPC 12

Note: the original meta SPC 2 was split into the current meta SPC 2 and meta SPC 12. The data required from a phys-chem perspective is comparable. Therefore, the data was copied below.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20	Visual	The test substance	liquid	Kenodin –

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
°C and 101.3 kPa		is the formulation of SPC 1.2.1		analysis, [redacted], 2015, 5/1.2.1
	Visual	The test substance is the formulation of SPC 1.2.2	liquid	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	Visual	The test substance is the formulation of SPC 1.2.3	liquid	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	Visual	The test substance is the formulation of SPC 1.2.4	liquid	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
Colour at 20 °C and 101.3 kPa	Visual	The test substance is the formulation of SPC 1.2.1	Dark brown	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	Visual	The test substance is the formulation of SPC 1.2.2	Dark brown	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	Visual	The test substance is the formulation of SPC 1.2.3	Dark brown	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	Visual	The test substance is the formulation of SPC 1.2.4	Dark brown	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
Odour at 20 °C and 101.3 kPa	Olfactory	The test substance is the formulation of SPC 1.2.1	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 1.2.2	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 1.2.3	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
	Olfactory	The test substance is the formulation of SPC 1.2.4	pungent	SDS Iodine, SQM, 2015, 2.3/13/2
Acidity / alkalinity	CIPAC MT 75.3	The test substance is the formulation of SPC 1.2.1	5.69 at 21°C	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	CIPAC MT 75.3	The test substance is the formulation	3.99 at 22°C	Kenodin Film – analysis,

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		of SPC 1.2.2		[redacted], 2015, 5/1.2.2
	CIPAC MT 75.3	The test substance is the formulation of SPC 1.2.3	5.52 at 24.5°C	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	CIPAC MT 75.3	The test substance is the formulation of SPC 1.2.4	5.39 at 22.5°C	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
	OECD 122		No test according to OECD 122 has been provided as the pH is between 4-10	
eCA remark The reported pH values are specifications. The actual measurements fall within this range. One of the products, Kenodin Film, has a pH of slightly below 4: 3.99 at 22°C, which formally means the acidity should be determined. The same formulation was tested for stability and the pH at the initial time stamp was above 4, but after storage, the pH decreased to below 4. Formulation 1.2.1: 5.56 Formulation 1.2.2: 3.99 Formulation 1.2.3: 5.52 Formulation 1.2.4: 5.39				
Relative density / bulk density	OECD Test guideline 109	The test substance is the formulation of SPC 1.2.1	1.041 g/cm³ at 20.5°C	Kenodin – analysis, [redacted], 2015, 5/1.2.1
	OECD Test guideline 109	The test substance is the formulation of SPC 1.2.2	1.041 g/cm³ at 21.0°C	Kenodin Film – analysis, [redacted], 2015, 5/1.2.2
	OECD Test guideline 109	The test substance is the formulation of SPC 1.2.3	1.035 g/cm³ at 19.0°C	Kenodin 5000 – analysis, [redacted], 2015, 5/1.2.3
	OECD Test guideline 109	The test substance is the formulation of SPC 1.2.4	1.032 g/cm³ at 19.0°C	Kenodin SD 5000 – analysis, [redacted], 2015, 5/1.2.4
eCA remark The density values are specified ranges, not actually determined values. The actual measurements are: 1.041g/cm^3 at 20.5°C, 1.041 g/cm^3 at 21.0°C, 1.035 g/cm^3 at 19.0°C and 1.032 g/cm^3 at 19.0°C respectively.				
Storage stability test	/	/	Please see the	Storage

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
– **accelerated storage**			eCA summary below.	stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark

Meta SPC 2 formula F110, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.54	4.58	4.69
Density	1.016	1.015	1.015
%Iodine (%increase)	0.284 (-)	0.296 (+4.2)	0.286 (+0.7)

Meta SPC 2 formula F6, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.51	4.78
Density	1.058	1.057	1.054
Viscosity (mPa.s, 10rpm)	2940	2710	2550
%Iodine (%increase)	0.522 (-)	0.530 (+1.5)	0.469 (-10.2)

Meta SPC 2 KENODIN, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.48	5.48
Density	1.037	1.038	1.039
Viscosity (mPa.s, 10rpm)	2000	3260	3820
%Iodine (%increase)	0.299 (-)	0.321 (+7.36)	0.339 (+13.4)

Meta SPC 2 KENODIN FILM, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	3.80	3.64
Density	1.028	1.023	1.027
Viscosity (mPa.s, 10rpm)	2972	2168	2316
%Iodine (%increase)	0.302	0.293 (-3.2%)	0.264 (-12.6%)

Meta SPC 2 KENODIN 5000, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.13	5.42

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Density	1.032	1.033	1.036
Viscosity (mPa.s, 10rpm)	2000	4520	4730
%Iodine (%increase)	0.500	0.451 (-9.8)	0.489 (-2.2)

Meta SPC 2 KENODIN SD5000, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.31	5.01
Density	1.034	1.030	1.032
%Iodine (%increase)	0.530 (-)	0.496 (-6.9)	0.471 (-11.1)

Meta SPC 2 formula F8, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.00	4.82
Density	1.017	1.017	1.017
%Iodine (%increase)	0.473 (-)	0.443 (-6.3)	0.412 (-12.9)

Meta SPC 2 KENODIN 2500, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.38	5.23	4.97
Density	1.016	1.036	1.038
%Iodine (%increase)	0.244 (-)	0.269 (+10.2)	0.271 (+11.1)
Viscosity (mPa.s)	2460	2170	2150

Meta SPC 2 formula F7, stored 8 weeks at 40°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.66	5.77
Density	1.028	1.025	1.036
%Iodine (%increase)	0.261 (-)	0.280 (+7.3)	0.282 (+8.0)
Viscosity (mPa.s)	2420	2360	2120

The active substance content decreased by more than 10% from the initial content for some formulations. Efficacy data was generated, which is included in the confidential annex.

The applicant has also indicated that errors occurred during some studies and they were therefore restarted. What these errors are exactly was not indicated. Therefore, the eCA cannot assess what the consequence of these errors should be. All data is summarised above and the eCA has not found any reason for concern with regard to the validty of the test results.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	/	/	Please see the eCA summary below.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark
The applicant has provided the data reported below. However, they have also indicated that errors occurred during some studies and they were therefore restarted. What these errors are exactly was not indicated. All data is summarised above and the eCA has not found any reason for concern with regard to the validty of the test results.

Some products showed a decrease in active substance content of >10%. This decrease was addressed using efficacy data. See the confidential annex (paragraph 3.4) for details on details on tested formulations and concentrations.

When the active substance degrades by more than 10%, the influence of such degradation with regard to hazard should be addressed. Considering iodine is a non-specific oxidiser, it is considered acceptable that the breakdown products are not identified. The breakdown products should be iodide ions and oxidised material. What compounds are formed is difficult to identify. It is not expected any specific hazardous compounds are formed in the process.

Meta SPC 2 formula F5, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.14	4.94	5.02	4.84	4.82	4.75
Density	1.016	1.014	1.015	1.014	1.015	1.016	1.015
%Iodine (%increase)	0.268 (-)	0.259 (-3.4)	0.258 (-3.7)	0.252 (-6.0)	0.248 (-7.5)	0.244 (-9.0)	0.242 (-9.7)

Meta SPC 2 formula F6, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.67	5.61	5.60	5.30	5.02	4.93
Density	1.058	1.061	1.062	1.063	1.062	1.063	1.061
Viscosity (mPA.s, 10rpm)	2940	2770	3110	3130	3110	3290	3970
%Iodine (%increase)	0.522 (-)	0.562 (+7.7)	0.575 (+10.2)	0.527 (+0.96)	0.539 (+3.3)	0.472 (-9.6)	0.469 (-10.2)

Meta SPC 2 KENODIN, stored at 25°C in HDPE

Time	Initial	3	6	9	12	18	24

Property	Guideline and Method	Purity of the test substance (% (w/w)		Results		Reference	
		months	months	months	months	months	months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.73	5.70	5.63	5.66	5.61	5.08
Density	1.037	1.039	1.039	1.040	1.039	1.039	1.038
Viscosity (mPA.s, 10rpm)	2000	1560	1560	2116	1510	1620	2290
%Iodine (%increase)	0.299 (-)	0.314 (+5.0)	0.318 (+6.4)	0.333 (+11.4)	0.333 (+11.4)	0.321 (+7.4)	0.281 (-6.0)

Meta SPC 2 KENODIN FILM, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	3.99	3.98	3.88	3.72	3.54	3.52
Density	1.028	1.027	1.027	1.029	1.027	1.027	1.027
Viscosity (mPA.s, 10rpm)	2972	2648	2649	2620	2284	2308	2630
%Iodine (%increase)	0.302 (-)	0.286 (-5.3)	0.286 (-5.3)	0.271 (-10.3)	0.270 (-10.6)	0.277 (-8.3)	0.275 (-8.9)

Meta SPC 2 KENODIN 5000, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.61	5.59	5.55	5.54	5.56	5.35
Density	1.032	1.036	1.036	1.036	1.037	1.037	1.036
Viscosity (mPA.s, 10rpm)	2000	2280	2330	2100	2330	2360	2480
%Iodine (%increase)	0.500 (-)	0.479 (-4.2)	0.485 (-3.0)	0.487 (-2.6)	0.480 (-4.0)	0.475 (-5.0)	0.479 (-4.2)

Meta SPC 2 KENODIN SD5000, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.25	5.12	5.49	5.00	4.78	4.63
Density	1.034	1.031	1.032	1.039	1.032	1.033	1.032
%Iodine (%increase)	0.530 (-)	0.523 (-1.3)	0.517 (-2.5)	0.491 (-7.4)	0.491 (-7.4)	0.465 (-12.3)	0.458 (-13.6)

Meta SPC 2 Formula F8, stored at 25°C in HDPE

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.18	5.08	5.01	4.80	4.74	4.68
Density	1.017	1.017	1.018	1.018	1.018	1.018	1.018
%Iodine (%increase)	0.473 (-)	0.446 (-5.7)	0.446 (-5.7)	0.434 (-8.3)	0.440 (-7.0)	0.428 (-9.5)	0.427 (-9.7)

Meta SPC 1.2 KENODIN 2500, stored at 25°C in HDPE

Time	Initial	3 months	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.38	5.23	5.41	5.34	5.41	5.37	5.37
Density	1.016	1.039	1.026	1.021	1.021	1.021	1.021
%Iodine (%increase)	0.264 (-)	0.274 (+16.4)	0.275 (+4.2)	0.274 (+3.8)	0.279 (+5.7)	0.276 (+4.6)	0.274 (+3.8)
Viscosity (mPa.s)	2460	2240	2212	2250	1952	2220	2112

Formulation KENODIN 2500 was moved to meta SPC 11.

Meta SPC 2, formula 7, stored at 25°C in HDPE

Time	Initial	3m	6 months	9 months	12 months	18 months	24 months
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.50	5.97	5.92	5.93	5.84	5.36	4.95
Density	1.028	1.036	1.036	1.037	1.037	1.038	1.037
%Iodine (%increase)	0.261 (-)	0.279 (+6.9)	0.282 (+8.1)	0.286 (+9.6)	0.284 (+8.8)	0.259 (-0.77)	0.244 (-6.5)
Viscosity (mPa.s)	2420	2486	2726	2368	2348	2950	2080

Storage stability test – **low temperature stability test for liquids**	/	/	Please see the eCA summary below.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2

eCA remark

Meta SPC 2 formula F5, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.27	5.19	5.32
Density	1.016	1.015	1.015
%Iodine	0.268	0.266	0.268

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
(%increase)		(-0.75)	(+0)	

Meta SPC 2 formula F6, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.46	5.64	5.75
Density	1.058	1.055	1.053
Viscosity (mPa.s, 10rpm)	2940	2910	2490
%Iodine (%increase)	0.522 (-)	0.539 (+3,3)	0.540 (+3.4)

Meta SPC 2 KENODIN, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.30	5.79	5.93
Density	1.037	1.039	1.038
Viscosity (mPa.s, 10rpm)	2000	3520	4230
%Iodine (%increase)	0.299 (-)	0.299 (+0)	0.338 (+13.0)

Meta SPC 2 KENODIN FILM, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	4.13	4.31	4.19
Density	1.028	1.028	1.027
Viscosity (mPa.s, 10rpm)	2972	2900	2864
%Iodine (%increase)	0.302	0.295 (-2.3)	0.302 (-)

Meta SPC 2 KENODIN 5000, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.58	5.72
Density	1.032	1.037	1.036
Viscosity (mPa.s, 10rpm)	2000	4352	4520
%Iodine (%increase)	0.500 (-)	0.510 (+2.0)	0.480 (-4.0)

Meta SPC 2 KENODIN SD5000, stored 8 weeks at 5°C in HDPE

Time	Initial	4w	8w
Appearance	Dark brown liquid	Dark brown liquid	Dark brown liquid
pH	5.45	5.42	5.48
Density	1.034	1.034	1.032
%Iodine (%increase)	0.530 (-)	0.537 (1.3)	0.520 (-1.9)

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td colspan="5">
Meta SPC 2 formula F8, stored 8 weeks at 5°C in HDPE
<table>
<tr><td>Time</td><td>Initial</td><td>4w</td><td>8w</td></tr>
<tr><td>Appearance</td><td>Dark brown liquid</td><td>Dark brown liquid</td><td>Dark brown liquid</td></tr>
<tr><td>pH</td><td>5.50</td><td>5.32</td><td>5.27</td></tr>
<tr><td>Density</td><td>1.017</td><td>1.018</td><td>1.018</td></tr>
<tr><td>%Iodine
(%increase)</td><td>0.473
(-)</td><td>0.485
(+2.5)</td><td>0.470
(-0.63)</td></tr>
</table>
Meta SPC KENODIN 2500, stored 8 weeks at 5°C in HDPE
<table>
<tr><td>Time</td><td>Initial</td><td>4w</td><td>8w</td></tr>
<tr><td>Appearance</td><td>Dark brown liquid</td><td>Dark brown liquid</td><td>Dark brown liquid</td></tr>
<tr><td>pH</td><td>5.38</td><td>5.31</td><td>5.17</td></tr>
<tr><td>Density</td><td>1.016</td><td>1.035</td><td>1.039</td></tr>
<tr><td>%Iodine
(%increase)</td><td>0.244
(-)</td><td>0.251
(+2.9)</td><td>0.258
(+5.7)</td></tr>
<tr><td>Viscosity (mPa.s)</td><td>2460</td><td>2210</td><td>2270</td></tr>
</table>
Formulation KENODIN 2500 was moved to meta SPC 11.

Meta SPC formula F7, stored 8 weeks at 5°C in HDPE
<table>
<tr><td>Time</td><td>Initial</td><td>4w</td><td>8w</td></tr>
<tr><td>Appearance</td><td>Dark brown liquid</td><td>Dark brown liquid</td><td>Dark brown liquid</td></tr>
<tr><td>pH</td><td>5.50</td><td>5.80</td><td>6.14</td></tr>
<tr><td>Density</td><td>1.028</td><td>1.038</td><td>1.040</td></tr>
<tr><td>%Iodine
(%increase)</td><td>0.261
(-)</td><td>0.267
(+2.3)</td><td>0.265
(+1.5)</td></tr>
<tr><td>Viscosity (mPa.s)</td><td>2420</td><td>2330</td><td>2080</td></tr>
</table>
The products tested are considered stable at 5°C. However, the tests should be performed at 0°C to negate the need of the a storage restriction for low temperatures. The storage conditions require the restriction ’Protect from frost’.
</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the biocidal product - light</td><td>/</td><td>/</td><td>Not relevant as the commercial packagings are not transparent.

Moreover stability tests have been done in the commercial packaging</td><td>CID LINES</td></tr>
<tr><td>Effects on content of the active substance and technical characteristics of the</td><td>/</td><td>/</td><td>Please refer to the shelf-life data</td><td>Storage stability tests of meta SPC 2, Cirlam</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
biocidal product – **temperature and humidity**				Laboratory, 3.4.1/1.2
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	/	/	No reactivity towards container material. This is included by the stability report because stability is done in commercial packaging.	Storage stability tests of meta SPC 2, Cirlam Laboratory, 3.4.1/1.2
Wettability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Suspensibility, spontaneity and dispersion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Wet sieve analysis and dry sieve test	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Requirements, version 1.1, ECHA, November 2014
Emulsifiability, re-emulsifiability and emulsion stability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Disintegration time	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Particle size distribution, content of dust/fines, attrition, friability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Persistent foaming	/	/	Not relevant because the product is ready to use and therefor	Guidance on the BPR, Volume I: Identity/physico-chemical

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			doesn't need to be diluted with water.	properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Flowability/Pourability/Dustability	/	/	Not relevant because the product is a liquid.	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning rate — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Burning completeness — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	/	/	Not relevant because there is no generation of smoke when using the products as described on the labels	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Spraying pattern — aerosols	/	/	Not relevant because the products are not aerosol	Guidance on the BPR, Volume I: Identity/physico-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Physical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Chemical compatibility	/	/	Not relevant because the products may not be used in combination with other products.	CID LINES
Degree of dissolution and dilution stability	/	/	Not relevant because the products should not be diluted with water	CID LINES
Surface tension	/	/	Kenodin SD 5000 has a surface tension of 29.86 mN/m	Guidance on the BPR, Volume I: Identity/physic

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			at 20°C at 100% v/v. Kenodin, Kenodin Film and Kenodin 5000 have a dynamic viscosity more than 200 mPa/s. According to the OECD 115 it is clearly stated under 'Initial Considerations' that measurement of surface tension is restricted to aqueous solutions with a dynamic viscosity of less than 200 mPa.	o-chemical properties / analytical methodology – part A: Information Requirements, version 1.1, ECHA, November 2014
Viscosity	OECD Test guideline 114	The test substance is the formulation of SPC 1.2.1	1500-6000 cP	Kenodin – analysis, Chenu, J., 2015, 5/1.2.1
	OECD Test guideline 114	The test substance is the formulation of SPC 1.2.2	2000-6000 cP	Kenodin Film – analysis, Chenu, J., 2015, 5/1.2.2
	OECD Test guideline 114	The test substance is the formulation of SPC 1.2.3	1500-6000 cP	Kenodin 5000 – analysis, Chenu, J., 2015, 5/1.2.3

eCA remark
The applicant reasons surface tension data is not required considering the product's visocity. The eCA considers that the reasoning is acceptable. The ring method will become less accurate with increasing viscosity. Based on the composition of this meta SPC, the product is expected to be surface active as it contains a significant amount of surfactants. Still, based on the considerations of the OECD test guideline, a viscosity determination is not required.

For the viscosity, acceptable data is available.

Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	CLP regulation		The Biocidal Product Family does not contain ingredients which are classified as explosive. Therefore we can consider this Family as non explosive.	
eCA remark The screening criteria outlined in appendix 6 of the UN manual for tests and criteria can be used to predict whether the products within the family need to be considered for classification. The groups indicated as inducing explosive potential are not present in the products of this family. The products are therefore not explosive in the sense of Regulation (EC) 1272/2008.				
Flammable gases	CLP regulation		The Biocidal Product Family does not contain products which are gases.	
Flammable aerosols	CLP regulation		The Biocidal Product Family does not contain products which are aerosols or pressurized containers.	
Oxidising gases	CLP regulation		The Biocidal Product Family does not contain products which are gases.	
Gases under pressure	CLP regulation		Product Family does not contain gases under pressure.	
Flammable liquids	CLP regulation		The Biocidal Product Family	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			does not contain ingredients which are flammable liquids. Therefore a flashpoint determination is not required and we can consider this Family as non flammable.	
eCA remark Based on the absence of compounds with a flashpoint ≤60°C at a significant concentration, the waiver by the applicant is considered acceptable.				
Flammable solids	CLP regulation		The Biocidal Product Family does not contain products which are solids.	
Self-reactive substances and mixtures	CLP regulation		The Biocidal Product Family does not contain self-reactive substances	
Pyrophoric liquids	CLP regulation		Due to high water content and known experience none of the formulations of the biocidal product family is expected to have pyrophoric properties.	
eCA remark The products within the family do not spontaneously ignite upon contact with air taking into account the storage stability data at elevated temperatures and are therefore not considered to be pyrophoric.				
Pyrophoric solids	CLP regulation		Not applicable. All products of this biocidal product family are water	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			based, ready to use liquid products.	
Self-heating substances and mixtures	CLP regulation		Due to high water content and known experience none of the formulations of the biocidal product family is expected to be self-heating.	
eCA remark The guidance on the application of CLP criteria states the following: *In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating. However, if liquids are adsorbed on a large surface (e.g. on powder particles), a self-heating hazard should be considered.* Furthermore, self-heating is not expected as the moieties related to self-reactiveness are not present. No screening data, as outlined in appendix 6 of the UN manual for tests and criteria, is available however, but considering the above, this should not be required.				
Substances and mixtures which in contact with water emit flammable gases	CLP regulation		Not applicable. None of the components of the product is classified as a substance and mixtures which in contact with water emits flammable gases	
eCA remark Although iodine could in theory induce internal reactions within a product, the eCA accepts that it is not likely the products needs to be classified. The products are not expected to ignite spontaneously in contact with air (pyrophoric behaviour), are not self-heating or self-igniting (no self-heating components) and are not expected to emit flammable gases in contact with water considering the products are aqueous.				
Oxidising liquids	CLP regulation		The Biocidal Product Family does not contain ingredients which are classified as oxidising. Therefore we can consider	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			this Family as not oxidising.	
eCA remark The waiver is not strictly correct, considering iodine is able to oxidise compounds. However, it is not able to donate oxygen, nor does it have the functional groups as specified in the appendix 6 of the UN manual for tests and criteria. Therefore it is not classified as oxidising.				
Oxidising solids	CLP regulation		The Biocidal Product Family does not contain products which are solids.	
Organic peroxides	CLP regulation		The Biocidal Product Family does not contain ingredients which are organic peroxides.	
Corrosive to metals	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula Kenodin SD 400 of metaSPC 1 (we have only 1 formula in this metaSPC, no range)	Not corrosive to aluminium nor steel (max weight loss 3.31%) No localized corrosion (pitting).	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F6 (maximum active substance and maximum co-formulants) of the old metaSPC 2 before splitting into metaSPC 2 and the new metaSPC 12 because of risk assessment reasons. This test formula is representative as worst-case for both the new metaSPCs 2 and 12.	Not corrosive to aluminium nor steel (max weight loss 0.41%) No localized corrosion (pitting)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method	The test substance	Not corrosive to	Corrosion test

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	is Formula F10 (maximum active substance and maximum co-formulants) of metaSPC 3	aluminium nor steel (max weight loss 1.22%) No localized corrosion (pitting)	report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula Kenodin SD of metaSPC 4 (we have only 1 formula in this metaSPC, no range)	Not corrosive to aluminium nor steel (max weight loss 0.29%) No localized corrosion (pitting)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F18 (maximum active substance and maximum co-formulants) of metaSPC 5	Not corrosive to aluminium nor steel (max weight loss 0.19%) No localized corrosion (pitting)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula Dermades PVP of metaSPC 6 (we have only 1 formula in this metaSPC, no range)	Not corrosive to aluminium nor steel (max weight loss 0.47%) No localized corrosion (pitting)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F25 (minimum active substance and minimum co-formulants) of metaSPC 7	Corrosive to metals (max weight loss 1.59%) In steel, localized corrosion was observed (intrustion depth 514µm, which exceeds the 120µm classification threshold).	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method	The test substance	Corrosive to	Corrosion test

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	is Formula F26 (maximum active substance and maximum co-formulants) of metaSPC 7	aluminium but not to inox (max weight loss 25.67%)	report: Determination of corrosion F26 M.SPC 1.7 (pure), Degryse J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F29 (minimum active substance and minimum co-formulants) of metaSPC 8	Corrosive to metals (max weight loss 15.43%)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F30 (maximum active substance and maximum co-formulants) of metaSPC 8	Corrosive to aluminium but not to inox (max weight loss 27.20%)	Corrosion test report: Determination of corrosion F30 M.SPC 1.8 (pure), Degryse J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F53 (minimum active substance and minimum co-formulants) of metaSPC 9	Corrosive to metals (max weight loss 29.55%)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula F55 (maximum active substance and maximum co-formulants) of metaSPC 9	Corrosive to aluminium but not to inox (max weight loss 93.28%)	Corrosion test report: Determination of corrosion F55 M.SPC 1.9 (pure), Degryse J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula Kenodin SD 900 of metaSPC 10 (we have only 1 formula in this metaSPC, no range)	Not corrosive to aluminium nor steel (max weight loss 0.09%) No localized corrosion (pitting)	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16
	Test method based on UN no. ST/SG/AC.10/11/Rev.4 guidelines	The test substance is Formula Kenodin 2500 of metaSPC 11 (we have only 1 formula in this metaSPC, no range)	Not corrosive to aluminium nor steel (max weight loss 0.17%) No localized corrosion	Corrosion test report: Determination of corrosion BPF Iodine, Platteau J., 2018, 4.16

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(pitting)	

eCA remark
For the composition of the model formulations used, please refer to the confidential annex.

Meta SPC1:
The meta SPC has a fixed concentration and the only product of this meta SPC was tested negative on the corrosion test. Therefore, meta SPC1 is not classified as corrosive to metals.

Meta SPC2:
Meta SPC2 has an iodine concentration of 0.3%. To represent meta SPC2 a formulation was tested that belonged to this meta SPC before it was split, with the maximum active substance and co-formulant concentrations. It is assumed this would represent a worst-case and the test was negative. Therefore, the products within meta SPC2 and 12 are not classified as corrosive to metals

Meta SPC3:
A model formulation was tested with the maximum amount of iodine and co-formulants assumed to represent the worst case. The study indicates the products within meta SPC3 do not need to be classified as corrosive to metals.

Meta SPC4:
Like meta SPC1, meta SPC4 has a fixed concentration and the only product of this meta SPC was tested negative on the corrosion test. Therefore, meta SPC4 is not classified as corrosive to metals.

Meta SPC5:
A model formulation was tested with the maximum amount of iodine and co-formulants assumed to represent the worst case. The study indicates the products within meta SPC5 do not need to be classified as corrosive to metals.

Meta SPC6:
Like meta SPC1, meta SPC6 has a fixed concentration and the only product of this meta SPC was tested negative on the corrosion test. Therefore, meta SPC6 is not classified as corrosive to metals.

Meta SPC7:
Two model formulations were tested, representing a worst and a best case (highest iodine and co-formulant concentration and lowest iodine and co-formulant concentration respectively). Both products were tested to be corrosive to metals, meaning all products within meta SPC7 should be classified.

Meta SPC8:
The same testing strategy as for meta SPC7 was used. The outcome is the same: the products within meta SPC8 are classified as corrosive to metals.

Meta SPC9:
The same testing strategy as for meta SPC7 was used. The outcome is the same: the products within meta SPC9 are classified as corrosive to metals.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Meta SPC10: Like meta SPC1, meta SPC10 has a fixed concentration and the only product of this meta SPC was tested negative on the corrosion test. Therefore, meta SPC10 is not classified as corrosive to metals. Meta SPC11: Like meta SPC1, meta SPC11 has a fixed concentration and the only product of this meta SPC was tested negative on the corrosion test. Therefore, meta SPC11 is not classified as corrosive to metals. Meta SPC12: See meta SPC2. The meta SPC is not classified as corrosive to metals. Conclusion: H290 is assigned to products within meta SPCs 7 – 9. All other meta SPCs (1-6, 10-12) are not classified as corrosive to metals.				
Auto-ignition temperatures of products (liquids and gases)	CLP regulation	BPF iodine based products – CID LINES NV	Not relevant	
eCA remark The auto-ignition temperature was not addressed for this family. Auto-ignition temperatures are hard to predict and the CLP regulation does not allow clear waiving options. Still, considering the high water content, auto-ignition at a temperature of concern is not expected. Iodine, the main component of concern, boils at approximately 184°C and does not decompose and is not expected to induce ignition of products.				
Relative self-ignition temperature for solids	CLP regulation	BPF iodine based products – CID LINES NV	Not relevant	
eCA remark Although iodine could in theory induce internal reactions within a product, the eCA accepts that it is not likely the products needs to be classified as none of the components within the family are self-igniting or auto-flammable.				
Dust explosion hazard	CLP regulation	BPF iodine based products – CID LINES NV	Not relevant, all products within the family are liquids.	

Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
0.32% iodine solution	Titration	6x	0.99989	To demonstrate the specificity of the method placebos of each Iodine Meta SPC were titrated; no equivalent points were found for Meta SPC 1, Meta SPC 2, Meta SPC 3, Meta SPC 4, Meta SPC 7, Meta SPC 8 and Meta SPC 9 meaning that only iodine is titrated.	95-105	0.302	1.495	0.035	Validation report: Determination of Iodine content in Iodine Meta SPC
2.5% PVP-iodine solution	Titration	6x	1.00000	To demonstrate the specificity of the method placebos of each PVP-Iodine Meta SPC were titrated; no equivalent points were found for Meta SPC 5 and Meta SPC 6 meaning that only iodine is titrated.	95-105	0.264	0.135	0.044	Validation report: Determination of Iodine content in PVP-Iodine Meta SPC
Methods for relevant impurities and substances of concern Not relevant.Technical iodine does not contain relevant impurities and the family does not include substances of concern that may be formed upon storage.									

<u>eCA evaluation of the analytical methods for the formulations within the family</u>

The family includes products based on PVP-iodine and surfactant stabilised iodine (iodophores 2 and 1 respectively). The same method is used to determine the active substance content in the products. The validation is reported in two separate reports, one for each iodophore type.

1) Iodine based products

Principle of method SOP/LP/ANA/C011 for the determination of iodine in formulations.

Depending on the expected concentration of iodine in the test material, an aliquot of test material is transferred to a plastic beaker. The sample is dissolved in demi water to a

volume of 60mL. Titration is done using 0.1M sodium thiosulfate using an automated titrator.

Validation
Validation is performed using a number of formulations. Placebo formulations were used to determine specificity and accuracy. These formulations contain the maximum amount of excipients for each meta SPC to maximize any matrix effects.

Specificity
Nine placebos were titrated for each meta SPC (meta SPC 1 is combined with 10 and SPC 2 is combined with 11). The experiment confirmed that only iodine is titrated.

Linearity
Linearity is addressed using 0.32% iodine solution and taking 8 – 48g samples (n=5), then titrating them. This resulted in a linear correlation between the volume of titrant and mass of the iodine solution with an r^2 of 0.99989, an intercept of -0.1459 and a slope of 4.125.

Accuracy
Placebos (spiked blank formulations) were made for each meta SPC. Three solutions were made and titrated to investigate recoveries.

Meta SPC 1 and meta SPC 10:	102.8%, 102.1% and 101.4%.
Meta SPC 2, meta SPC 11 and meta SPC 12:	97.7%, 100.3%, 100.7%
Meta SPC 3:	100.4%, 100.7%, 100.7%
Meta SPC 4:	100.4%, 100.0%, 100.0%
Meta SPC 7:	102.3%, 100.7%, 100.0%
Meta SPC 8:	102.0%, 100.7%, 100.0%
Meta SPC 9	104.0%, 102.3%, 103.6%:

Precision
3 analysts have analysed 6 consecutive times a 0.32% iodine solution. The %RSD observed were 0.442%, 0.341% and 0.585% for the three analysts respectively. At 1%, the allowed RSD is 2.68 according to the Horwitz equation. At lower concentration, the RSD is allowed to be even higher. Therefore, it is concluded that the method is sufficiently precise.

Conclusion
Method validation is acceptable.

2) PVP_iodine based products
Principle of method SOP/LP/ANA/C011 for the determination of iodine in formulations.

Depending on the expected concentration of iodine in the test material, an aliquot of test material is transferred to a plastic beaker. The sample is dissolved in demi water to a volume of 60mL. Titration is done using 0.1M sodium thiosulfate using an automated titrator.

Validation
Validation is performed using a number of formulations. Placebo formulations were used to determine specificity and accuracy. These formulations contain the maximum amount of excipients for each meta SPC to maximize any matrix effects.

Specificity

Nine placebos were titrated for meta SPC 5 and 6. The experiments confirmed that only iodine is titrated.

Linearity
Linearity is addressed using 2.5% PVP-iodine solutions and taking 10 – 60g samples (n=5), then titrating them. This resulted in a linear correlation between the volume of titrant and mass of the iodine solution with an r^2 of 1.000, an intercept of +0.0424 and a slope of 4.571.

Accuracy
Placebos (spiked blank formulations) were made for each meta SPC. Three solutions were made and titrated to investigate recoveries.

metaSPC 5	102.3%, 100.0%, 100.0%
metaSPC 6	96.6%, 100.0%, 100.0%

Precision
3 analysts have analysed 6 consecutive times a 2.5% PVP-iodine solution (approximately 0.25% iodine). The %RSD observed were 0.072%, 0.058% and 0.111% for the three analysts respectively. At 1%, the allowed RSD is 2.68 according to the Horwitz equation. At lower concentration, the RSD is allowed to be even higher. Therefore, it is concluded that the method is sufficiently precise.

Conclusion
Method validation is acceptable.

Analytical methods for soil - Note of the applicant:
MoA in soil compartment is not necessary according to the CAR on iodine because exposures in soil are lower than natural occurring iodine contents in soil. This is also shown in the environmental risk assessment reports (Part 9 of the IUCLID 5.6.0 file).

Analytical methods for air - Note of the applicant:
We are advised in the CAR on iodine to investigate on Method of Analysis in the air compartment in order to better estimate or refine the exposure of workers. Nevertheless air is not a relevant compartment and exposures of workers are detailed in the human risk assessment reports (Part 8 of the IUCLID 5.6.0 file). Therefore further investigation in methods of analysis in air is not necessary.

Analytical methods for water - Note of the applicant:
MoA in water compartment is not necessary according to the CAR on iodine because exposures in water are lower than natural occurring iodine contents in water. This is also shown in the environmental risk assessment reports (Part 9 of the IUCLID 5.6.0 file).

Analytical methods for animal and human body fluids and tissues - Note of the applicant:
As described in the CAR on iodine, iodine is an essential dietary trace element for mammals (especially for the synthesis of thyroid hormones). No recommendations on development of MoA for animal and human body fluids and tissues are found in the CAR. Moreover iodine exposure in animal body is described in the Livestock risk assessment reports (Part 8 of the IUCLID 5.6.0 file) and human exposure is described in the Human risk assessment reports (part 8 of the IUCLID 5.6.0 file). Conclusions show an acceptable risk for both mammals and humans. Therefore no further investigation on MoA is necessary.

Analytical methods for residues in food and feeding stuff - Note of the applicant:
MoA to determined residues in food (especially milk) is considered in the CAR on iodine. Nevertheless, detailed calculations on exposure are presented in the human risk assessment reports (Part 8 of the IUCLID 5.6.0 file). It shows that exposure is expected to be safe therefore no further investigation on MoA in food is necessary.

Efficacy against target organisms

D. FUNCTION AND FIELD OF USE

Meta SPC 1
Post-milking teat disinfectant based on iodine (concentrated) for veterinary use (PT3).

Meta SPC 2
Post-milking teat disinfectant based on iodine (ready to use) for veterinary use (PT3).

Meta SPC 3
Animal skin disinfectant based on iodine (ready to use) for veterinary use (PT3).

Meta SPC 4
Animal teat disinfectant based on iodine (ready to use) for veterinary use (PT3).
Animal skin disinfectant based on iodine (ready to use) for veterinary use (PT3).

Meta SPC 5
Post-milking teat disinfectant based on PVP-iodine (ready to use) for veterinary use (PT3).

Meta SPC 6
Animal skin disinfectant based on PVP-iodine (ready to use) for veterinary use (PT3).

Meta SPC 7
Surface disinfectant based on iodine (concentrated) for use in veterinary field (PT3) with bactericidal, yeasticidal and virucidal activity.
Surface disinfectant based on iodine (concentrated) for use in food industry (PT4) with bactericidal and yeasticidal activity.

Meta SPC 8
Surface disinfectant based on iodine (concentrated) for use in veterinary field (PT3) with bactericidal, yeasticidal and virucidal activity.
Surface disinfectant based on iodine (concentrated) for use in food industry (PT4) with bactericidal and yeasticidal activity.

Meta SPC 9
CIP disinfectant based on iodine (concentrated) for disinfection of milking machines and CIP installations in food industry (PT4).

MetaSPC 10
Post-milking teat disinfectant based on iodine (concentrated) for veterinary use (PT3)

MetaSPC 11
Post-milking teat disinfectant based on iodine (ready to use) for veterinary use (PT3).

Meta SPC 12
Post-milking teat disinfectant based on iodine (ready to use) for veterinary use (PT3).

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

Below the claimed groups of organisms are mentioned with the test organisms per *meta* SPC.

Meta SPC 1– Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 2 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 3 – Skin disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*
Yeasts: *Candida albicans*

Meta SPC 4 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 4 – Skin disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*
Yeasts: *Candida albicans*

Meta SPC 5 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 6 – Skin disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*
Yeasts: *Candida albicans*

Meta SPC 7 – PT3 – Surface disinfection
Bacteria: *Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 7 – PT4 – Surface disinfection
Bacteria: *Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*

Meta SPC 8 – PT3 – Surface disinfection
Bacteria: *Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 8 – PT4 – Surface disinfection
Bacteria: *Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*

Meta SPC 9 – CIP disinfection
Bacteria: *Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*

Meta SPC 10 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Meta SPC 11 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*

Meta SPC 12 – Teat disinfection
Bacteria: *Streptococcus uberis, Escherichia coli, Staphylococcus aureus*
Yeasts: *Candida albicans*
Viruses: ECBO

Organisms to be protected:
Animals and humans

F. EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING

Killing of bacteria, yeasts and viruses.

G. MODE OF ACTION, INCLUDING TIME DELAY

Information from the Iodine CAR:

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

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

The rapid penetration of iodine into microorganisms and its mode of action indicate that the time-delay i.e. contact time required for sufficient efficacy depends on the tolerance of the organism to iodine and the concentration of iodine used for treatment. Iodine is more effective at higher temperatures.
The biocidal activity of iodine-containing solutions is characterised by their colour. Amber solutions are active whilst pale yellow or colourless solutions are less effective and must be replaced by new solutions.

Information from the "Antiseptics and disinfectants: Activity, Action, and Resistance":
Iodine is rapid, even at low concentrations, but the exact mode of action is unknown. Iodine rapidly penetrates into microorganisms and attacks key groups of proteins (in particular the free-sulfur amino acids cysteine and methionine, nucleotides, and fatty acids, which culminates in cell death. Less is known about the antiviral action of iodine, but nonlipid viruses and parvoviruses are less sensitive than lipid enveloped viruses. Similarly to bacteria, it is likely that iodine attacks the surface proteins of enveloped viruses, but they may also destabilize membrane fatty acids by reacting with unsaturated carbon bonds.

H. EFFICACY DATA

Meta SPC 1: CONCENTRATED POST-MILKING TEAT DISINFECTANTS, BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:

This *meta* SPC is completely covered by the efficacy data presented in *meta* SPC 2.
The ready to use formulas are comparable to the formulas comprised on the meta SPC 2.
The product has to be diluted with water before application and allows a final concentration of 0.3% (w/w) available iodine. Moreover, the content of the other ingredients in meta SPC 1 are comprised within the range of meta SPC 2.
Therefore tests done with meta SPC 2 products are stated in the table below.

Stability of diluted formulation

Only 1 test has been done on a *meta* SPC1 product in order to proof that the product in dilution is still efficient after 1 week storage.
The product has to be diluted with water before application and allows a final concentration of 0.3% (w/w) available iodine.
The test (EN1656) has been performed with worst case product of this meta SPC. The test cover all possible products in dilution within the meta SPC:

- The active substance content in the test formula is at the minimum concentration of the meta SPC after dilution with water, which is 0.3% iodine.
- Minimum of all excipients after dilution with water

The test was not redone with the maximum of all ingredients expected to have negative influence on the efficacy because we noticed from the tests done on formulas F5 and F37 of meta SPC 2 that the same results can be expected.
The test results are summarised in the table below.

Choice organims

Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*)), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*).
The stability test is performed with the most resistant organism (*streptococcus uberis*) based on the EN1656 test.

Choice Test conditions

For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion meta SPC 1

Products have proven bactericidal, yeasticidal and virucidal efficacy in 5 min.

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**
Post-milking teat disinfecta	Use in veterinary field (PT3)	Meta SPC 1 Formula F1: -1%	*Streptococcus uberis*	EN1656	Milk conditions 30°C Contact time: 5 min	Works at 80%	*2016-02-005*

nt (to be diluted)		available iodine -Minimum of all excipients In dilution (0.3% Iodine) after 1 week storage at 25°C			Concentr.: 80%		
		Meta SPC 2 Formula F5: -0.25% available iodine -Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-005*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-012*
		Meta SPC 2 Formula F90: -0.3% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-041* *2016-06-041*
			ECBO	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-02-036*
		Meta SPC 2 F37 Formula: -0.25% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-009*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 2: RTU POST-MILKING TEAT DISINFECTANTS,BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:
All test (EN1656, EN1657, EN16437 simulated skin test, EN14675) have been performed with worst case products of this meta SPC. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas (F37 and F90) is at or below the minimum concentration of the meta SPC, which is 0.3% iodine.
- Maximum content of the excipients with negative influence on the efficacy.
- Minimum of other excipients

The test results are summarised in the table below.

Choice organisms
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*)), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*).

Choice Test conditions
For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion:
Products have proven bactericidal, yeasticidal and virucidal efficacy in 5 min.

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**
Post-milking teat disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 2 Formula F37: -0.25% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-009*
			Streptococcus uberis, Escherichia coli, Staphylococcus aureus	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 10%, 40%, 80%	Works at 40%	*2016-06-043*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*
		Meta SPC 2 Formula F90: -0.3% available iodine -Maximum of	*Streptococcus uberis, Staphylococcus aureus, Escherichia coli*	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-041* *2016-06-041*
			ECBO	EN14675	Milk conditions	Works at	*2016-02-*

		negative influence excipients** -Minimum of other excipients			30°C Contact time: 5 min Concentr.: 80%	80%	*036*
		Meta SPC 2 Formula F8: -Maximum available iodine (0,5%) -Maximum of negative influence excipients -Minimum of other excipients	*ECBO*	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-10-014*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 3: UDDER DISINFECTANT FOR USE ON INTACT SKIN, BACTERICIDAL AND YEASTICIDAL

Justification:
All tests (EN1656, EN1657, EN16437 simulated skin test, EN14675) have been performed with worst case products of this meta SPC. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas is the minimum concentration of the meta SPC, which is 0.3% iodine.
- Both maximum and minimum content of the excipients with negative influence on the efficacy have been tested
- Minimum of other excipients

The test results are summarised in the table below.

Choice organisms:
For most tests micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus, Streptococcus uberis, Streptococcus suis* and *Staphylococcus hyicus*) as well as of yeasts (*Candida albicans*).
The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation (see waiver below).

Choice Test conditions
For skin disinfection a contact time of 5 minutes, temperature of 30°C and dirty conditions (10 g/L bovine albumin + 10 g/L yeast extract) was respected.

Conclusion:
Products have proven bactericidal and yeasticidal efficacy in 5 min for use as skin disinfectant on intact skin of:
-dairy and beef cattle on the udder before calving
-sows on the udder before farrowing.

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**
Skin disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 3 Formula F9: -0.3% available iodine - Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*	EN1656	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*MetaSPC 1.3 (min-min F9) EN1656_dirty.PDF MetaSPC 1.3 (min-min F9)_EN1656_dirty_add. strains.PDF (2015-05-010 and 2015-05-036)*
			Candida albicans	EN1657	Dirty conditions 30°C Contact time:	Works at 80%	*MetaSPC 1.3 (min-min F9)_EN1657_C.a._dirty.PDF 2015-05-014*

					5 min Concentr.: 80%		
		Meta SPC 3 Formula F48: -0.3% available iodine - Maximum of negative influence excipients** - Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus, Pseudomonas aeruginosa*	EN1656	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*MetaSPC 1.3 (min-max neg F48)_EN1656_30Â°C_5min_dirty.PDF* *MetaSPC 1.3 (min-max neg F48)_EN1656_dirty_add.PDF* *2016-01-030*
			Candida albicans	EN1657	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*MetaSCP 1.3 (min-max neg F48)_EN1657__dirty.PDF*
			Pseudomonas aeruginosa	EN16437 simulated skin test	Dirty conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-042*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Waiver skin disinfection meta SPC 3

The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation.

Justification:

Pseudomonas aeruginosa is a difficult bacterial strain to control.

P. aeruginosa is chosen for this study, because it is a pathogen that is reported frequently in a veterinary and in a hospital setting [9] [10] [11]. Furthermore, this is also one of the organisms selected mostly in studies [3] [4] [5] [12].

The case study described by Beeckman et al., shows that an infection with *P. aeruginosa* is very difficult to overcome. The cows that were affected by the outbreak of subclinical mastitis caused by *P. aeruginosa* on this farm were treated with antibiotics and the milking equipment was disinfected with Atlantol 5% solution. Eventually, the treatment was unsuccessful. The *P. aeruginosa* infection only disappeared from the farm as soon as all infected cows were culled. [10] The same happened in the case report of Osborne et al. [11]

Hillier et al., describes a case in which skin lesions in dogs were caused by *P. aeruginosa*. Only 9 out of 20 dogs with this infection could be saved after a long treatment with antibiotics. [9]

In-vitro comparison

a. Minimum inhibitory concentration (MIC)

The study of Koburger et al. shows that for the iodine disinfectant, the minimum inhibitory concentration (MIC) is one of the highest when *P. aeruginosa* is used as a test organism, compared to other organisms. This is the case when we compare with other gram negative bacteria, with gram positive bacteria and with yeasts. Concrete, the MIC of *P. aeruginosa* is 1024, whilst the MIC for the gram positive *Staphylococcus aureus* is 512 and the one for the yeast *Candida albicans* is 256. [5]
The MIC was also highest compared to other gram-negative bacterial strains, in the study of Houang et al. The MIC of iodine-based disinfectant for *P. aeruginosa* is 1:512, the one for *E. coli* 1:4096, for *K. aerogenes* 1:4096 and the MIC for *S. marcenscens* is 1:8192. [3]
The MIC for *P. aeruginosa* is also the highest of all organisms tested, when chlorhexidine and triclosan is used as disinfectant. [4] [5] *P. aeruginosa* is equally as resistant to iodine then *E. coli.* Both have a MIC of 1024. [5]

b. Killing time

The study of Houang et al. [3] shows the time that an iodine-based disinfectant needs to kill different gram-negative strains. The time needed to kill *P. aeruginosa* was longer than those of the other organisms tested. More specifically, up to 5 minutes were necessary to kill *P. aeruginosa,* whilst for *E. coli* 15 seconds, for *K. aerogenes* 1 minute and for *S. marcescens* 30 seconds were necessary. [3]

c. Ex-vivo tests

The ex-vivo tests on skin described by Messager et al., shows that *P. aeruginosa* is one of the most resistant bacterial strains when tested with an iodine-based disinfectant because the log reduction of viable bacteria is one of the lowest. [12]
These studies show that *P. aeruginosa* is one of the most difficult strains to kill with an iodine based disinfectant.

[3] E. Houang, O. Gilmore, C. Reid and E. Shaw, "Absence of bacterial resistance to povidone iodine," *Journal of clinical pathology,* vol. 29, pp. 752-755, 1976.

[4] G. McDonnell and A. Russel, "Antiseptics and disinfectants: activity, action and resistance," *Clinical Microbiology Reviews,* vol. 12, no. 1, pp. 147-179, 1999.

[5] T. Koburger, N.-O. Hübner, M. Braun, J. Siebert and A. Kramer, "Standardized comparison af antiseptic efficacy of triclosan, PVP-iodine, octenidine dihydrochloride, polyhexanide and chlorhexidine digluconate," *Journal of Antimicrobial Chemotherapy,* vol. 65, pp. 1712-1719, 2010.

[9] A. Hillier, J. Alcorn, J. Cole and J. Kowalski, "Pyoderma caused by Pseudomonas aeruginosa infection in dogs: 20 cases.," *Veterinary dermatology,* vol. 17, no. 6, pp. 432-439, 2006.

[10] D. Beeckman, S. De Vliegher, G. Hoflack, G. Opsomer and A. de Kruif, "Subclinical Pseudomonas aeruginosa mastitis in a dairy herd," *Vlaams diergeneeskundig tijdschrift,* vol. 72, pp. 108-111, 2003.

[11] A. Osborne, K. Armstrong, N. Catrysse, G. Butler and L. Versavel, "An outbreak of Pseudomonas mastitis in dairy cows," *Canadian veterinary journal,* vol. 22, pp. 215-217, 1981.

[12] S. Messager, P. Goddard, P. Dettmar and J.-Y. Maillard, "Determination of the antibacterial afficacy of several antiseptics tested on skin by an ex-vivo test," *Journal of medical microbiology,* vol. 50, pp. 284-292, 2001.

Meta SPC 4: UDDER AND POST-MILKING TEAT DISINFECTANTS, BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:

This *meta* SPC is completely covered by the efficacy data presented in *meta* SPC 2 (= teat disinfection) and *meta* SPC 3 (= skin disinfection).
The ready to use formulas are comparable to the formulas comprised on the meta SPC 2 and meta SPC 3. The product is ready to use and allows a final concentration of 0.3% (w/w) available iodine. Moreover the content of the other ingredients in meta SPC 4 are comprised within the range of meta SPC 2 and meta SPC 3.

Choice organisms

See *meta*-SPC 2 for teat disinfection and *meta*-SPC 3 for skin disinfection. For most tests micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus, Streptococcus uberis, Streptococcus suis (only for animal skin disinfection)* and *Staphylococcus hyicus (only for animal skin disinfection)*)), strains of viruses (ECBO) (only for teat disinfection) as well as of yeasts (*Candida albicans*).
The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation (see waiver Meta 3).

Choice Test conditions

For skin disinfection a contact time of 5 minutes, temperature of 30°C and dirty conditions (10 g/L bovine albumin + 10 g/L yeast extract) was respected.
For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion:

For teat disinfection products have a proven bactericidal, yeasticidal and virucidal efficacy in 5 min.
For skin disinfection products have a proven bactericidal and yeasticidal efficacy in 5 min.

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**
Skin disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 3 Formula F9: -0.3% available iodine -Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus*	EN1656	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-010* *and* *2015-05-036*
			Candida albicans	EN1657	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-014*

		Meta SPC 3 Formula F48: -0.3% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus, pseudomonas aeruginosa*	EN1656	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-048* *2015-06-061* *2016-01-030*
			Pseudomonas aeruginosa	EN1656	Dirty conditions 15°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-03-024*
			Pseudomonas aeruginosa ***	EN16437 simulated skin test	Dirty conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2015-06-037*
			Candida albicans	EN1657	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-01-042*
Post-milking teat disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 2 Formula F5: -0.25% available iodine -Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-005*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-012*
		Meta SPC 2 Formula F37: -0.25% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-009*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-02-036*

		Meta SPC 2 Formula F90: -0.3% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-041* *2016-06-041*
			ECBO	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

***The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation.

Justification: see metaSPC 3

Meta SPC 5: RTU POST MILKING TEAT DISINFECTANTS, PVP-IODINE, BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:
All tests (EN1656, EN1657, EN16437 simulated skin test, EN14675) have been performed with worst case products of this meta SPC. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas is at or below the minimum concentration of the meta SPC, which is 3% PVP-iodine.
- Maximum content of the excipients with negative influence on the efficacy.
- Minimum of other excipients

The test results are summarised in the table below.

Choice organisms:
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*)), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*)
The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation (see waiver Meta 3).

Choice Test conditions
For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion:
Products have a proven bactericidal, yeasticidal and virucidal efficacy in 5 min.

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**
Post-milking teat disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 5 Formula F17: -2.5% active substance (PVP iodine***) - Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-006*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-13*
		Meta SPC 5 Formula F39: -2.5%	*Streptococcus uberis, Escherichia coli, Staphyloco*	EN1656	Milk conditions 30°C Contact time:	Works at 80%	*2015-06-014*

		active substance (PVP iodine***) - Maximum of negative influence excipients** - Minimum of other excipients	*ccus aureus*		5 min Concentr.: 80%		
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-033*
			Streptococcus uberis	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	Iodine Meta SPC 1.5 F39_EN16437_drop.dip_milk.S.u.pdf *2016-01-047*
			Escherichia coli, Staphylococcus aureus	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-06-042*
		Meta SPC 5 Formula F84: -3% active substance (PVP iodine***) - Minimum of all excipients	*ECBO*	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-10-015*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

*** In the test formulations containing PVP Iodine, the concentration available iodine is between 9-12% of the PVP iodine concentration. This concentration may decrease during aging but would then be more worst case for efficacy testing.

Meta SPC 6: UDDER DISINFECTANTS, PVP IODINE, BACTERICIDAL AND YEASTICIDAL

Justification:

All tests (EN1656, EN1657, EN16437 simulated skin test, EN14675) have been performed with worst case products of this meta SPC, since the composition of the meta SPC does not include a range of concentrations. The test formula F21 is the only possible composition in meta SPC 6.

Choice organisms:
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus, Streptococcus uberis, Streptococcus suis* and *Staphylococcus hyicus*) as well as of yeasts (*Candida albicans*)
The EN16437 has only been done on the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation (see waiver Meta 3).

Choice Test conditions
For skin disinfection a contact time of 5 minutes, temperature of 30°C and dirty conditions (10 g/L bovine albumin + 10 g/L yeast extract) was respected.

Conclusion:
Products have a proven bactericidal and yeasticidal efficacy in 5 min.

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**
Skin disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 6 Formula F21: -10% active substance (PVP iodine**) -Minimum of all excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus, Streptococcus suis, Staphylococcus hyicus, pseudomonas aeruginosa,*	EN1656	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-011* *2015-05-037* *2016-01-031*
			Candida albicans	EN1657	Dirty conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-015*
			Pseudomonas aeruginosa	EN16437 simulated skin test	Dirty conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*Annex 1 Protocol modified EN16437.pdf* *2016-01-048*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.
** In the test formulations containing PVP Iodine, the concentration available iodine is between 9-12% of the PVP iodine concentration. This concentration may decrease during aging but would then be more worst case for efficacy testing.

Meta SPC 7 and Meta SPC 8 – PT3: CONCENTRATED SURFACE DISINFECTANTS IODINE, BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:

The meta SPC 8 is completely covered by meta SPC 7 for use as surface disinfectants in PT3.

The concentrated formulas of meta SPC 8 are comparable to the formulas comprised in the meta SPC 7. Moreover the content of the other ingredients in meta SPC 8 are comprised within the range of meta SPC 7 except for phosphoric acid.

All tests (EN1656, EN1657, EN14349, EN16438 and EN14675) have been performed with worst case products of this meta SPC. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas is below the minimum concentration of the meta SPC 7, which is 1.8% iodine.
- Minimum (Formula F25) and maximum content of the excipients with negative influence on the efficacy (Formula F62) of metaSPC 7.
- Minimum of other excipients of meta SPC 7.

The test results are summarised in the table below.

Choice organisms:

Micro-organisms were chosen according to the EN standards: strains of bacteria (*Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris* and *Staphylococcus aureus*), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*).

Choice Test conditions

For surface disinfection a contact time of 30 minutes, temperature of 10°C and clean conditions (3 g/L bovine albumin) was respected.

Contact time:

The new PT3 guidance (Vol II part B+C) states a maximum contact time of 30 minutes. Tests with the product F62 demonstrate efficacy with a contact time of 30 minutes. When this dossier was submitted in 2015 this guidance was not available yet. At that time the TNsG for product authorisation and EN14885 where available as guidance. In these no maximum contact time is set and EN14885 mentions that test can be done at 60min contact time. Therefore, the contact time of 60 minutes for the 2015-06-055 test is accepted by the e-CA.

Conclusion:

For PT3, products have a proven bactericidal, yeasticidal and virucidal efficacy.

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**
Surface disinfectant (concentrated)	Use in veterinary field (PT3)	Meta SPC 7 Formula F25: -1% available iodine -Minimum of all	*Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus*	EN1656	Clean conditions 10°C Contact time: 30 min Concentr.: 0.5%-1%-1.5%	Works at 1.5%	*2015-07-028*

		excipients	*Candida albicans*	EN1657	Clean conditions 10°C Contact time: 30 min Concentr.: 0.5%-1%-1.5%	Works at 1.5%	*2015-07-013*
			Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus	EN14349	Clean conditions 10°C Contact time: 30 min Concentr.: 2%-2.5%-3%	Works at 2.5%	*2015-06-078*
			Candida albicans	EN16438	Clean conditions 10°C Contact time: 60 min Concentr.: 2%-2.5%-3%	Works at 2.5%	*2015-06-055*
			ECBO	EN14675	Clean conditions 10°C Contact time: 30 min Concentr.: 3%-3.5%-4%	Works at 3.5%	*MetaSPC (F25) EN14675_low level soiling.PDF 2015-07-056*
		Meta SPC 7 Formula F62: -1% available iodine -Maximum of negative influence excipients ** -Minimum of other excipients	*Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus*	EN1656	Clean conditions 10°C Contact time: 30 min Concentr.: 0.5%-1%-1.5%	Works at 1.5%	*2015-07-049*
			Candida albicans	EN1657	Clean conditions 10°C Contact time: 30 min Concentr.: 0.5%-1%-1.5%	Works at 1.5%	*2015-07-039*
			Enterococcus hirae, Pseudomonas aeruginosa, Proteus vulgaris, Staphylococcus aureus	EN14349	Clean conditions 10°C Contact time: 30 min Concentr.: 2%-2.5%-3%	Works at 2.5%	*2015-07-034*
			Candida albicans	EN16438	Clean conditions 10°C Contact time: 30 min Concentr.:	Works at 2.5%	*2018-09-017*

					2%-2.5%-3%		
			ECBO	EN14675	Clean conditions 10°C Contact time: 30 min Concentr.: 3%-3.25%-3.50%	Works at 3.5%	*2016-02-041*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 7 and Meta SPC 8 –PT4: CONCENTRATED SURFACE DISINFECTANTS IODINE, BACTERICIDAL AND YEASTICIDAL

Justification

The meta SPC 8 is completely covered by meta SPC 7 for use as surface disinfectants in PT4.

The concentrated formulas of meta SPC 8 are comparable to the formulas comprised in the meta SPC 7. Moreover the content of the other ingredients in meta SPC 8 are comprised within the range of meta SPC 7 except for phosphoric acid.

All tests (EN1276, EN1650 and EN13697) have been performed with worst case products of this meta SPC. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas is below the minimum concentration of the meta SPC, which is 1.8% iodine.
- Minimum (Formula F25) and maximum content of the excipients with negative influence on the efficacy (Formula F62).
- Minimum of other excipients

The test results are summarised in the table below.

Choice organisms

PT4: One of the EN13697 tests has only been carried out with the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation.

Justification: One of the EN13697 tests has only been carried out with the strain *Pseudomonas aeruginosa* because this can be considered being the most resistant organism to perform the testing on for this formulation.

In the other efficacy tests micro-organisms were chosen according to the EN standards: strains of bacteria (*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli* and *Staphylococcus aureus*) as well as of yeasts (*Candida albicans*).

Choice Test conditions

For surface disinfection a contact time of 5 minutes for bactericidal activity, a contact time of 15 minutes for yeasticidal activity, temperature of 20°C and clean conditions (0.3 g/L bovine albumin) was respected.

Conclusion:

For PT4 products have a proven bactericidal and yeasticidal efficacy.

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**
Surface disinfectant (concentrated)	Use in Food industry (PT4)	Meta SPC 7 Formula F25: -1% available iodine -Minimum of all excipients	*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*	EN1276	Clean conditions 20°C Contact time: 5 min Concentr.: 0.1%-0.25%-0.5%	Works at 0.5%	*2015-07-015*
			Candida	EN1650	Clean	Works	*2015-06-077*

			albicans		conditions 20°C Contact time: 15 min Concentr.: 0.25%-0.5%-0.75%	at 0.5%	
			Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Candida albicans	EN1369 7	Clean conditions 18-25°C Contact time: 5 min (bacteria) 15 min (yeast) Concentr.: 1.5%-2%-2.5% (bacteria) 0.75%-1%-1.25%	Bacteria: Works at 2% Yeast: Works at 1.25% %	*2015-07-019*
		Meta SPC 7 Formula F62: - 1% available iodine -Maximum of negative influence excipients ** -Minimum of other excipients	*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*	EN1276	Clean conditions 20°C Contact time: 5 min Concentr.: 0.1%-0.25%-0.5%	Works at 0.5%	*2015-07-050*
			Candida albicans	EN1650	Clean conditions 20°C Contact time: 15 min Concentr.: 0.25%-0.5%-0.75%	Works at 0.5%	*2015-07-037*
			Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus, Candida albicans	EN1369 7	Clean conditions 18-25°C Contact time: 5 min (bacteria) 15 min (yeast) Concentr.: 1.5%-2%-2.5% (bacteria) 0.75%-1%-1.25%	Bacteria: Works at 2% Yeast: Works at 1.25% %	*2015-07-031*
			Pseudomonas	EN1369	Clean	Works	*2016-01-051*

			aeruginosa (1)	7	conditions 18-25°C Contact time: 15 min Concentr.: 1.5%-2%-2.5%	at 1.5%	

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 9 – PT4: CIP DISINFECTANTS IODINE, BACTERICIDAL AND YEASTICIDAL

Justification:
All tests (EN1276 and EN1650) have been performed with worst case products of this meta SPC. No phase 2 step 2 suspension test is required for CIP disinfection. The tests cover all possible products within the meta SPC:

- The active substance content in the test formulas is the minimum concentration of the meta SPC, which is 0.5% iodine.
- Minimum (Formula F53) content of the excipients with negative influence and maximum content of most of the excipients with negative influence on the efficacy (Formula F42).
- Minimum of other excipients

The test results are summarised in the table below.

Choice organisms
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli* and *Staphylococcus aureus*) as well as of yeasts (*Candida albicans*).

Choice Test conditions
For CIP disinfection a contact time of 5 minutes for bactericidal activity, a contact time of 15 minutes for yeasticidal activity, temperature of 20°C and clean conditions (0.3 g/L bovine albumin) was respected.

Conclusion
Products have a proven bactericidal and yeasticidal efficacy.

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**
CIP disinfectant (concentrated)	Use in Food industry and milking machines (PT4)	Meta SPC 9 Formula F53: -0.5% available iodine -Minimum of all excipients	*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus*	EN1276	Clean conditions 20°C Contact time: 5 min Concentr.: 0.1%-0.25%-0.5%	Works at 0.25%	*2015-07-026*
			Candida albicans	EN1650	Clean conditions 20°C Contact time: 15 min Concentr.: 0.1%-0.25%-0.5%	Works at 0.25%	*2015-07-035*
		Meta SPC 7 Formula F42: -0.5% available iodine	*Enterococcus hirae, Pseudomonas aeruginosa, Escherichia coli,*	EN1276	Clean conditions 20°C Contact time: 5 min Concentr.:	Works at 0.25%	*2015-07-027*

		-Maximum of negative influence excipients ** -Minimum of other excipients	*Staphylococcus aureus*		0.1%-0.25%-0.5%		
			Candida albicans	EN1650	Clean conditions 20°C Contact time: 15 min Concentr.: 0.1%-0.25%-0.5%	Works at 0.25%	*2017-07-036*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 10: CONCENTRATED TEAT DISINFECTANTS, IODINE, BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification
This *meta* SPC is completely covered by the efficacy data presented in *meta* SPC 2.
The ready to use formulas are comparable to the formulas comprised on the meta SPC 2.
The product has to be diluted with water before application and allows a final concentration of 0.3% (w/w) available iodine. Moreover the content of the other ingredients in meta SPC 10 are comprised within the range of meta SPC 2.

Therefore we refer to the efficacy tests done for meta SPC 2 to prove the efficacy of the products in meta SPC 10.

In order to prove that the product in dilution is still efficient after 1 week storage, we refer to the test presented for meta SPC 1.
The product has to be diluted with water before application and allows a final concentration of 0.3% (w/w) available iodine, just as the products comprised in meta SPC 1.

Choice organisms
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*).

Choice Test conditions
For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusions
Products have proven bactericidal, yeasticidal and virucidal efficacy in 5 min

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**
Post-milking teat disinfectant (to be diluted)	Use in veterinary field (PT3)	Meta SPC 1 Formula F1: -1% available iodine -Minimum of all excipients In dilution (0.3% Iodine) after 1 week storage at 25°C	*Streptococcus uberis*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-02-005*
		Meta SPC 2 Formula F5:	*Streptococcus uberis, Escherichia*	EN1656	Milk conditions 30°C Contact time:	Works at 80%	*2015-05-005*

		-0.25% available iodine -Minimum of all excipients	*coli, Staphylococcus aureus*		5 min Concentr.: 80%		
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-012*
		Meta SPC 2 Formula F90: -0.3% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-041* *2016-06-041*
			ECBO	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-02-036*
		Meta SPC 2 F37 Formula: -0.25% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-009*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Meta SPC 11: PT3 RTU TEAT DISINFECTANTS, IODINE, BACTERICIDAL AND YEASTICIDAL

Justification:
For this meta SPC tests were waived and test for meta SPC 2 were used for the evaluation. The ready to use formulas of meta SPC 11 are comparable to the ready to use formulas initially tested for the meta SPC 2. This meta SPC 11 was created because the concentration of 0.25% iodine does not provide virucidal activity.

Choice organisms
Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*).

Choice Test conditions
For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion
Products have proven bactericidal and yeasticidal efficacy in 5 min, but has no virucidal efficacy.

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**
Post-milking teat disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 2 Formula F5: -0.25% available iodine -Minimum of all excipients Representative for meta SPC 11	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-005*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-05-012*
			Streptococcus uberis, Escherichia coli, Staphylococcus aureus	Modified EN16437	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-03-174*
			ECBO	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Does not work at 80% ***	*2015-04-062*
		Meta SPC 2 Formula F37: -0.25% available	*Streptococcus uberis, Escherichia coli,*	EN1656	Milk conditions 30°C Contact time: 5 min	Works at 80%	*2015-06-009*

		iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Staphylococcus aureus*		Concentr.: 80%		
			Streptococcus uberis, Escherichia coli, Staphylococcus aureus	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 10%, 40%, 80%	Works at 40%	*2016-06-043*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

*** With this test we see that meta SPC 11 has no virucidal activity.

Meta SPC 12: RTU POST-MILKING TEAT DISINFECTANTS,BACTERICIDAL, YEASTICIDAL AND VIRUCIDAL

Justification:

For this meta SPC tests were waived and test for meta SPC 2 were used for the evaluation. The ready to use formulas of meta SPC 12 are comparable to the ready to use formulas initially tested for the meta SPC 2. This meta SPC 12 was created because of HHRA reasons.

All tests (EN1656, EN1657, EN16437 simulated skin test, EN14675) have been performed with worst case products of the meta SPC 2. The tests cover all possible products within the meta SPC 12:

- The active substance content in the test formulas (F37 and F90) is at or below the minimum concentration of the meta SPC 12, which is 0.3% iodine.
- Maximum content of the excipients with negative influence on the efficacy of meta SPC 12.
- Minimum of other excipients in meta SPC 12

The test results are summarised in the table below.

Choice organisms

Micro-organisms were chosen according to the EN standards: strains of bacteria (*Escherichia coli*, *Staphylococcus aureus* and *Streptococcus uberis*), strains of viruses (ECBO) as well as of yeasts (*Candida albicans*)

Choice Test conditions

For post-milking a contact time of 5 minutes, temperature of 30°C and milk conditions (10 g/L skimmed milk) was respected.

Conclusion:

Products have proven bactericidal, yeasticidal and virucidal efficacy in 5 min.

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 /**	**Test results*: effects**	**Reference**

					exposure time		
Post-milking teat disinfectant (ready to use)	Use in veterinary field (PT3)	Meta SPC 2 Formula F37: -0.25% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Escherichia coli, Staphylococcus aureus*	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-009*
			Streptococcus uberis, Escherichia coli, Staphylococcus aureus	EN1656	Milk conditions 30°C Contact time: 5 min Concentr.: 10%, 40%, 80%	Works at 40%	*2016-06-043*
			Candida albicans	EN1657	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-06-034*
		Meta SPC 2 Formula F90: -0.3% available iodine -Maximum of negative influence excipients** -Minimum of other excipients	*Streptococcus uberis, Staphylococcus aureus, Escherichia coli*	EN16437 simulated skin test	Milk conditions 30°C Contact time: 5 min Concentr.: 100%	Works at 100%	*2016-01-041*
			ECBO	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2016-02-036*
		Meta SPC 2 Formula F8: -Maximum available iodine (0,5%) -Maximum of negative influence excipients** -Minimum of other excipients	*ECBO*	EN14675	Milk conditions 30°C Contact time: 5 min Concentr.: 80%	Works at 80%	*2015-10-014*

* Works at 80% means that the log reduction needed to pass the test is reached at 80% product concentration.

** The reasoning of negative influence excipients is indicated in the confidential annex.

Conclusion on the efficacy of the products

The tests demonstrate the efficacy of the products in the meta SPC's according to the use instruction as stated in the SPC and in authorised use section 2.2.1.C. Below an overview.

Skin and Teat Disinfectants			
meta SPC 1 - Concentrated teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Milk conditions
Yeasticidal activity	0,3%	5 min	Milk conditions
Virucidal activity	0,3%	5 min	Milk conditions
meta SPC 2 - Ready to use teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Milk conditions
Yeasticidal activity	0,3%	5 min	Milk conditions
Virucidal activity	0,3%	5 min	Milk conditions
meta SPC 3 - Ready to use skin disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Dirty conditions
Yeasticidal activity	0,3%	5 min	Dirty conditions
meta SPC 4, use 4.1 - Ready to use teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Milk conditions
Yeasticidal activity	0,3%	5 min	Milk conditions
Virucidal activity	0,3%	5 min	Milk conditions
meta SPC 4, use 4.2 - Ready to use skin disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Dirty conditions
Yeasticidal activity	0,3%	5 min	Dirty conditions
meta SP 5 - Ready to use teat disinfectants (PT3) based on PVP-iodine			
	The use concentration of PVP-iodine	**Contact time**	**Test Conditions**
Bactericidal activity	3,0%	5 min	Milk conditions
Yeasticidal activity	3,0%	5 min	Milk conditions
Virucidal activity	3,0%	5 min	Milk conditions
meta SPC 6 - Ready to use skin disinfectants (PT3) based on PVP-iodine			
	The use concentration of PVP-iodine	**Contact time**	**Test Conditions**
Bactericidal activity	10%	5 min	Dirty conditions
Yeasticidal activity	10%	5 min	Dirty conditions
meta SPC 10 -Concentrated teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Milk conditions
Yeasticidal activity	0,3%	5 min	Milk conditions

Virucidal activity	0,3%	5 min	Milk conditions
meta SPC 11 - Ready to use teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,25%	5 min	Milk conditions
Yeasticidal activity	0,25%	5 min	Milk conditions
Virucidal activity	0,25%	5 min	Milk conditions
meta SPC 12 - Ready to use teat disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0,3%	5 min	Milk conditions
Yeasticidal activity	0,3%	5 min	Milk conditions
Virucidal activity	0,3%	5 min	Milk conditions

Surface Disinfectants

meta SPC 7, use 7.2 - Concentrated Surface disinfectants (PT3) based on iodine and meta SPC 8, use 8.2 Concentrated Surface disinfectants (PT3) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0.025%	30 min	Clean conditions
Yeasticidal activity	0.025%	30 min	Clean conditions
Virucidal activity	0.035%	30 min	Clean conditions
meta SPC 7, use 7.1 - Concentrated Surface disinfectants (PT4) based on iodine and meta SPC 8, use 8.1 Concentrated Surface disinfectants (PT4) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0.015%	15 min	Clean conditions
Yeasticidal activity	0.0125%	15 min	Clean conditions
meta SPC 9 - CIP disinfectantys (PT4) based on iodine			
	The use concentration of iodine	**Contact time**	**Test Conditions**
Bactericidal activity	0. 00125%	5 min	Clean conditions
Yeasticidal activity	0.00125%	15 min	Clean conditions

I. OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT

Information from the Iodine CAR:
Taking into account the mode of action of iodine which is non-specific, 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.

J. KNOWN LIMITATIONS

Note of the applicant: not applicable.

K. EVALUATION OF THE LABEL CLAIMS

The label claims as stated in the SPC reflect the efficacy of the biocidal product.

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

Note of the applicant: not applicable. The product is not intended to be used with other products.

Risk assessment for human health

Products from metaSPC 2 and 5 are identical to the example product in the CAR, therefore only the summary is presented below.

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

Corrosion and irritation to skin is determined according to the CLP regulation for each metaSPC.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	• metaSPC 1: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 2: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 3: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 4: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 5: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 6: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 7: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 8: products are considered as corrosive for skin according to the CLP regulation. • metaSPC 9: products are considered as corrosive for skin according to the CLP regulation. • metaSPC 10: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 11: products are not considered as irritants for skin according to the CLP regulation. • metaSPC 12: products are not considered as irritants for skin according to the CLP regulation.
Justification for the value/conclusion	MetaSPC 1, 2, 3, 4, 5, 6, 7, 10 11 and 12 are not classified regarding skin corrosion/irritation. MetaSPC 8 is classified as H315 and 9 is classified as H314.
Classification of the product according to CLP and DSD	MetaSPC 1, 2, 3, 4, 5, 6, 7, 10, 11 and 12 are not classified regarding skin corrosion/irritation. MetaSPC 8 is classified as H315 and 9 is classified as H314.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	In accordance to the calculation method described in Annex I of Regulation 1272/2008/EC (CLP), metaSPC 1, 2, 3, 4, 5, 6, 7, 10, 11

	and 12 are not classified regarding skin corrosion/irritation. MetaSPC 8 is classified as skin irritant and MetaSPC9 is classified as corrosive for skin. No further testing is performed because unnecessary. Note eCA: all calculations for skin corrosion/irritation are included in the confidential Annex of the PAR.

Eye irritation

Eye irritation test on corneal epitheliums are performed for products of metaSPC 2, 3, 5 and 6 (metaSPC 4 is covered by metaSPC 2).
Note eCA: original metaSPC 2 was splitted in metaSPC 2, metaSPC11 and metaSPC 12

Eye irritation potential of products of metaSPC 1, 7, 8 and 9 is determined according to the calculation method described in Annex I of the CLP regulation 1272/2008/EC.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Results of eye irritation test show that products for metaSPC 2, 3, 4, 5, 6, 11 and 12 are not irritant for the eyes
Justification for the value/conclusion	Eye irritation test on corneal epitheliums are performed for products of metaSPC 2, 3, 5 and 6 (metaSPC 4, metaSPC11 and metaSPC12 are covered by metaSPC 2). Based on this test, no classification is warranted for eye irritating properties. Reports on eye irritation are provided in IUCLID 5.
Classification of the product according to CLP and DSD	Products of metaSPC 1, 7, 8 and 10 are classified as damaging for eyes H318 according to the CLP regulation. Products of metaSPC 9 are classified as corrosive for eyes H314. No further investigation is necessary.

Data waiving	
Information requirement	Study scientifically not justified for metaSPC 1, 7, 8, 9 and 10.
Justification	Classification of metaSPC 1, 7, 8, 9 and 10 is derived using the calculation rules in accordance to CLP. Products of metaSPC 1, 7, 8 and 10 are classified as damaging for eyes according to the CLP regulation. Products of metaSPC 9 are classified as corrosive for eyes. No further investigation is necessary.

Note by the eCA: The applicant has submitted new *in vitro* eye irritation tests in August 2019 for metaSPC2 (covering metaSPC4, 11 and 12), metaSPC3, metaSPC5 and metaSPC6. These *in vitro* test were fully in line with OECD testing guidelines and are included in the confidential annex.
Furthermore, the applicant has included the tested formulation in the provided Excel document *CTGB ALL biocidal_product_family_overview_en*. From this the following can be concluded (and included in the confidential Annex of the PAR, see section 5 CLP calculations for eye corrosion/ irritation):

- tested formulation for metaSPC2 is equal to the max. concentrations of the co-formulants with potential eye effects included this metaSPC, and worst case for metaSPC4, metaSPC11 and metaSPC12.

- tested formulation for metaSPC3 is equal to the max. concentrations of the co-formulants with potential eye effects included this metaSPC.
- tested formulation for metaSPC5 is equal to the max. concentrations of the co-formulants with potential eye effects included this metaSPC.
- tested formulation for metaSPC6 is equal to the max. concentrations included this metaSPC.

CLP calculations for eye irritations are provided in the confidential part of the PAR.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Products of the BPF are not classified as irritant for the respiratory tract according to the CLP regulation, as none of the components are classified for respiratory tract irritation.
Classification of the product according to CLP and DSD	Products of the BPF are not classified as irritant for the respiratory tract according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	Products of the BPF are not classified as irritant for the respiratory tract according to the CLP regulation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Product of the BPF are not classified as sensitising for skin according to the CLP regulation as mentioned in Part 8.3 of the IUCLID 5.6.0.
Justification for the value/conclusion	CLP regulation 1272/2008
Classification of the product according to CLP and DSD	Product of the BPF are not classified as sensitising for skin according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	Product of the BPF are not classified as sensitising for skin according to the CLP regulation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Product of the BPF are not classified as sensitising for the respiratory system according to the CLP regulation as mentioned in the IUCLID 5.6.0.
Justification for the value/conclusion	CLP regulation 1272/2008
Classification of the product according to CLP and DSD	Product of the BPF are not classified as sensitising for the respiratory system according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	Product of the BPF are not classified as sensitising for the respiratory system according to the CLP regulation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Products of the entire BPF are not classified as acute toxic by oral route
Justification for the selected value	CLP regulation 1272/2008
Classification of the product according to CLP and DSD	Products of the entire BPF are not classified as acute toxic by oral route according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	Products of the entire BPF are not classified as acute toxic by oral route according to the CLP regulation. Note eCA: all calculations for acute toxicity are included in the confidential Annex of the PAR.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Products of the entire BPF are not classified as acute toxic by inhalation route
Justification for the selected value	CLP regulation 1272/2008
Classification of	Products of the entire BPF are not classified as acute toxic by

the product according to CLP and DSD	inhalation route according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	Products of the entire BPF are not classified as acute toxic by inhalation route according to the CLP regulation. Note eCA: all calculations for acute toxicity are included in the confidential Annex of the PAR.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Products of the BPF are not classified as acute toxic by dermal route
Justification for the selected value	CLP regulation 1272/2008
Classification of the product according to CLP and DSD	Products of the BPF are not classified as acute toxic by dermal route according to the CLP regulation.

Data waiving	
Information requirement	Study scientifically unjustified
Justification	Products of the BPF are not classified as acute toxic by dermal route according to the CLP regulation. Note eCA: all calculations for acute toxicity are included in the confidential Annex of the PAR.

Information on dermal absorption

As member of IRG group, we have access to the study on percutaneous absorption performed on Iodine by IRG (OECD 428, section A6.2/10 of the IRG file). Study was performed on teat disinfectant ready-to-use products containing 0.26% to 0.66% of total iodine and shows a dermal penetration of 11.3% to 12.0%. The value of 12% is considered as relevant in the Assessment Report on Iodine (13 December 2013).

Value(s) used in the Risk Assessment – Dermal absorption			
Substance	Iodine		
Value(s)*	12% for metaSPC1-7, 10-12 MetaSPC9 is classified with H314: Causes severe skin burns and eye damage. For exposure calculations to the undiluted products included in these		

	metaSPCs, 100% dermal absorption needs to be considered. metaSPC8 is classified for skin irritant effects and therefore read across to the tested compounds included in the CAR is considered not acceptable. As the total amount of iodine is < 5% (i.e. 4.02%), the default for water based solutions of 50% is used for the dermal exposure assessment of the concentrated product. As the diluted product is not classified for irritant effects, 12% is used for dermal exposure assessment of the diluted products of metaSPC8 (discussed and agreed upon in WGIV2019).		
Justification for the selected value(s)	IRG study, Assessment Report on Iodine (13 December 2013)		

Data waiving	
Information requirement	Study scientifically unjustified (study already available for Iodine).
Justification	As member of IRG group, we have access to the study on percutaneous absorption performed on Iodine by IRG (OCDE 428, section A6.2/10 of the IRG file). Study was performed on teat disinfectant ready-to-use products containing 0.26% to 0.66% of total iodine and shows a dermal penetration of 11.3% to 12.0%. This value is considered as relevant in the Assessment Report on Iodine (13 December 2013).

	Note eCA: A justification for the dermal absorption value of 12% based on read across, including an overview of the BPF and the tested formulation, is included in a separate document. This document is prepared by the eCA and is only available for the MSs, as it includes information from the confidential part of the CAR of iodine.

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

SoCs identified in the BPF are, alcohols, C12 -15, ethoxylated, Alcohols C9-11+6 EO and phosphoric acid.

GESTIS database was consulted and no OEL was found for alcohols, C12 -15, ethoxylated. On the contrary an OEL (8 hours working day) of 1 mg/m³ is found for phosphoric acid.

More information and an evaluation is available in the confidential annex of the PAR.

eCA note: in line with guidance for the identification and evaluation of SoCs (CA-Nov14-Doc.5.11, included in BPR guidance human health part) both substances referred to are identified as substance of concern (i.e. alcohols, C12 -15, ethoxylated, Alcohols C9-11+6 EO and phosphoric acid).

all mentioned co-formulants add to the classification of the metaSPCs/product included in the metaSPCs.
Based on the BPR containing the SoCs at different concentrations, the SoCs end up in the following band: Band B.
Associated evaluation and risk management requirements for this band according to the table included in the guidance is:

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

Based on the classification either H318 or H314 (both part of Band B) of metaSPC/products included in metaSPC 1,7, 8, 9 and 10, P280: Wear protective gloves/protective clothing/eye protection/face protection is assigned. This risk mitigation is considered sufficient for this effect. (see also confidential annex to the PAR, paragraph 4)

Furthermore, for phosphoric acid an OELvalue of 1 mg/m³ is available. Based on the evaluation as included in the confidential annex to the PAR (paragraph 4) no risk is expected due to exposure to phosphoric acid by the use of products included in metaSPC 8 and 9.

Available toxicological data relating to a mixture

Iodine is classified with H372: Causes damage to thyroid through prolonged or repeated exposure, oral route. The classification limit for H373 is: H373 – 1.0 % ≤ concentration < 10 %

Based on the classification rules and the concentration of the active substance, metaSPC 1, 6, 7, 8 and 10 need to be classified with H373: May cause damage to organs thyroid through prolonged or repeated exposure, oral route.

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Commission Delegated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
c) the adverse effect is a consequence of the endocrine mode of action.

Potentially an alert is identified by the eCA for two co-formulants, i.e. the iodine equivalents containing substances that have been included in the risk assessment. As information for iodine and PVP-iodine on the ED assessment should be used for these iodine equivalents containing substances, the outcome of the EU discussions on the actives should be awaited for these two co-formulants (see confidential annex for more information).

To examine if any of the other co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property. See assessment included in the confidential annex.

Subsequently, it was examined if there are any concerns for adverse effect to meet the criteria a) as described above using ECHA REACH database. This examination did not result in alerts, and therefore no further ED assessment was required.

B. EXPOSURE ASSESSMENT

Details on exposure for each metaSPC is provided in the risk assessment reports available per metaSPC in Part 8 of the IUCLID 5.6.0.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes metaSPC 7 (PT4) 8 (PT4) 9 (Food Drink Milk industry (FDM))	Yes metaSPC: 1 and 10 2 and 11,12 3 4 5 6 7 (PT3) 8 (PT3) 9 (milking parlours)	No	n.a.	No	No	No
Dermal	Yes metaSPC 7 (PT4) 8 (PT4) 9 (FDM)	Yes metaSPC: 1 and 10 2 and 11, 12 3 4 5 6 7 (PT3) 8 (PT3) 9 (milking parlours)	No	n.a.	No	No	No

Oral	n.a.	No	No	See "via food"	See "via food"	See "via food"	Yes Possible metaSPC 1, 2, 3, 4, 5, 6, 7 (PT3), 8 (PT3), 7 (PT4), 8 (PT4), 9 (PT4), 10, 11, 12 (PT3)

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
metaSPC 1: PT3 concentrated teat disinfectants - Iodine			
1.	Mixing and loading of concentrates for dip cup or trigger sprayer or electronic sprayer-system or robotic milking device	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution. Automatic dilution (drawning of pure product) is covered by the manual dilution step	professionals
2.	Application on teats	Primary exposure dermal + inhalation (manual spraying of teats) Automatic spraying (robot) is covered by the manual spraying	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals
metaSPC 2: PT3: RTU teat disinfectants - Iodine			
1.1	Mixing and loading of RTUs for trigger sprayer or electronic sprayer	Primary exposure dermal + inhalation (pumping working solution in order to fill in trigger sprays)	professionals
1.2	Mixing and loading of RTUs for dip cup or automated sprayer	Primary exposure dermal + inhalation (pumping working solution in order to fill in trigger sprays or dip bottles)	professionals
2.	Application on teats	Primary exposure (dermal and inhalation exposure) for manual spraying (scenario 2.1) and dipping (scenario 2.2) (when using a robot milking machine, the worker is not exposed)	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals

metaSPC 3: PT3 RTU skin disinfectants - Iodine			
1.	Mixing and Loading of spraying application	Primary exposure (dermal and inhalation exposure) for loading the trigger spray.	professionals
2.1 and 2.2	Application on skin of udder of cow or sows before calving/farrowing	Primary exposure (dermal and inhalation exposure) for spraying on skin of udder of cow or sows before calving/farrowing	professionals
3.	cleaning equipment	Primary exposure (dermal and inhalation exposure) for cleaning spraying equipment.	professionals
metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine			
1.1	Mixing and loading of RTUs for trigger sprayer or electronic sprayer,	Primary exposure dermal + inhalation (pouring the pure product in a order to fill in trigger sprays).	professionals
1.2	Mixing and loading of RTUs for dip cup or automated sprayer	Primary exposure dermal + inhalation (pumping working solution in order to fill in trigger sprays or dip bottles)	professionals
2.	Application on teats	Primary exposure (dermal and inhalation exposure) for manual spraying (scenario 2.1) and dipping (scenario 2.2) (when using a robot milking machine, the worker is not exposed)	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals
Exposures following occasional uses of products from metaSPC 4 (up to 0.5% of total iodine) on skin are covered by exposure to products from metaSPC 3 also applied on skin (up to 1.45% of total iodine) which are covered from metaSPC 2 (up to 0.78% of total iodine). Therefore there is no need for further investigation.			
metaSPC 5: RTU teat disinfectant – PVP-Iodine			
Exposures following use of teat disinfectants from metaSPC 5 (up to0.57% of total iodine) are covered by the ones following use of teat disinfectants from metaSPC 2 (total iodine is maximum 0.78%). Therefore, there is no need for further investigation.			
metaSPC 6: RTU skin disinfectant - PVP-Iodine			
The same scenarios as included for metaSPC3.			
metaSPC 7: PT3 surfaces disinfectant - Iodine			

1.	Pouring step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
2.	Pumping step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
3.	Spraying	Primary exposure dermal + inhalation (spraying on surfaces)	professionals
metaSPC 8: PT3 surfaces disinfectant - Iodine			
1.	Pouring step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
2.	Pumping step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
3.	Spraying	Primary exposure dermal + inhalation (spraying on surfaces)	professionals
metaSPC 7: PT4 surfaces disinfectant - Iodine			
1.	Pouring step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
2.	Pumping step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
3.	Spraying	Primary exposure dermal + inhalation (spraying on surfaces)	professionals
metaSPC 8: PT4 surfaces disinfectant - Iodine			
1.	Pouring step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
2.	Pumping step	Primary exposure dermal + inhalation (to allow dilution of product in the back pulverisator)	professionals
3.	Spraying	Primary exposure dermal + inhalation (spraying on surfaces)	professionals
metaSPC 9: PT4 CIP disinfectants in food industry - Iodine			
1.	Pouring step	Primary exposure inhalation + dermal (in the case of professionals that have to pour pure product). Sometimes this step is automatized with a venture system.	professionals
2.	Pumping step	Primary exposure inhalation + dermal (in the case of professionals that have to pump pure product). Sometimes this step is automatized with a venture system.	professionals
metaSPC 9: PT4 CIP disinfectants for milking parlours - Iodine			
1.	Pouring step	Primary exposure inhalation + dermal (in the case of professionals that have to pour pure product). Sometimes this step is automatized with a venture system.	professionals
2.	Pumping step	Primary exposure inhalation + dermal (in the case of professionals that have to pump pure product). Sometimes this step is automatized with a venture system.	professionals
metaSPC 10: PT3 Concentrated teat disinfectants - Iodine			

1.	Mixing and loading of concentrates for trigger sprayer or electronic sprayer, or robotic milking device	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution. Automatic dilution (drawning of pure product) is covered by the manual dilution step	professionals
2.	Application on teats	Primary exposure dermal + inhalation (manual spraying of teats) Automatic spraying (robot) is covered by the manual spraying	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals
metaSPC 11 : PT3: RTU teat disinfectants - Iodine			
1.	Mixing and loading of concentrates for trigger sprayer or electronic sprayer, or robotic milking device	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution. Automatic dilution (drawning of pure product) is covered by the manual dilution step	professionals
2.	Application on teats	Primary exposure dermal + inhalation (manual spraying of teats) Automatic spraying (robot) is covered by the manual spraying	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals
metaSPC 12 : PT3: RTU teat disinfectants - Iodine			
1.	Mixing and loading of concentrates for trigger sprayer or electronic sprayer, or robotic milking device	Primary exposure dermal + inhalation (pouring the pure product in a bigger jerrycan to allow dilution step) for manual dilution. Automatic dilution (drawning of pure product) is covered by the manual dilution step	professionals

2.	Application on teats	Primary exposure dermal + inhalation (manual spraying of teats) (when using a robot milking machine, the worker is not exposed)	professionals
3.	Cleaning of teats	Primary exposure dermal + inhalation	professionals
4.	Cleaning of equipment	Primary exposure dermal + inhalation	professionals
Animal exposure			
1.	RTU teat treatment – animal exposure (meta SPC 1, 2, 4-6 and 10-12)	Primary animal exposure from teat treatment. Skin treatment for cow is considered comparable	Animals
2.	Skin disifection (meta SPC 3 and 4)	Primary exposure of sows before and after farrowing	Animals
3.	Animal house treatment by spraying – animal exposure (meta SPC 7 and 8)	Secondary animal exposure due to residues from spraying of animal houses.	Animals

Industrial exposure

metaSPC 7: PT4 Surfaces disinfectants - Iodine

Description of Scenario [1] pouring step - metaSPC 7: PT4 Surfaces disinfectants – Iodine		
Primary exposure (dermal + inhalation). This task is performed indoors. Dilution step is done by pouring the jerrycan of concentrate in the container where water will be released to in order to allow dilution. The task is done manually. This exposure is done on pure product (maximum 3.51% of total iodine). Frequency of application is maximum once per day, 5 days per week. The Model 7 for Mixing and Loading – pouring liquids is used. This model figures on the TNsG part II on human exposure to biocidal products and is revised in the HEEG Opinion 1 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, 2008. The indicative values of the HEEG Opinion 1 are stricter than the one of the TNsG Part II. To consider the very worst-case, the values of the HEEG Opinion 1 are used.		
	Parameters	Value
Tier 1	Dermal absorption	12%
	Respiration rate	0.021 m^3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	5 minutes
	Frequency	Maximum 1 time per day (worst-case)
	Indicative value dermal exposure	101 mg/min
	Indicative value inhalation	0.94 mg/m^3
Tier 2	Indicative value dermal exposure with gloves	1.01 mg/min

Description of Scenario [2] pumping step - metaSPC 7: PT4 Surfaces disinfectants – Iodine		
Primary exposure (dermal + inhalation). This task is performed indoors. Dilution step can be done by pumping the pure product from the jerrycan in the container where water will be released to in order to allow dilution. The task is done manually. This exposure is done on pure product (maximum 3.51% of iodine). Frequency of application is maximum once per day 5 days per week. The Model 7 for Mixing and Loading – pumping liquids is used. This model figures on the TNsG part II on human exposure to biocidal products and is revised in the HEEG Opinion 1 on the use of available data and models for the assessment pf the exposure of operators during the loading of products into vessels or systems in industrial scale, 2008. The indicative values of the HEEG Opinion 1 are stricter than the one of the TNsG Part II. To consider the very worst-case, the values of the HEEG Opinion 1 are used.		
	Parameters	Value
Tier 1	Dermal absorption	12%

	Respiration rate	0.021 m3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	5 minutes
	Frequency	Maximum 3 times per day (worst-case)
	Indicative value dermal exposure	138 mg/min
	Indicative value inhalation	22 mg/m3
Tier 2	Indicative value dermal exposure with gloves	1.38 mg/min

Description of Scenario [3] spraying step - metaSPC 7: PT4 Surfaces disinfectants – Iodine		
Primary exposure dermal + inhalation (spraying on surfaces). Working solution is sprayed on surfaces with a back pulverisator or an automatic sprayer. This step can take 1 to 2 hours depending on the surface to be disinfected. After a contact time of 15 minutes product is rinsed with water. The disinfection can be done up to 1 time per day, 5 days per week. This exposure is done with diluted product (0.025% of total iodine). According to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 2, the spraying model 1 is used. The potential dermal exposure to the working solution is 181 mg/min for hands outside protective gloves and 10.7 mg/min inside the gloves. The model gives an indicative value of 92 mg/min for body exposure. The first tier should be performed without PPE, meaning without gloves.		
	Parameters	Value
Tier 1	Dermal absorption	12%
	Respiration rate	0.021 m3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	2 hours (worst-case)
	Frequency	Once per day
	Indicative value dermal exposure (hands)	181 mg/min
	Indicative value dermal exposure (body)	92 mg/min
	Indicative value inhalation	104 mg/m3
Tier 2	Indicative value dermal exposure with gloves (hands)+ coated coverall	10.7 mg/min, and 90% protection for body exposure

metaSPC 8: PT4 Surfaces disinfectants - Iodine

Description of Scenario [1] pouring step - metaSPC 8: PT4 Surfaces disinfectants – Iodine

Primary exposure (dermal + inhalation). This task is performed indoors. Dilution step is done by pouring the jerrycan of concentrate in the container where water will be released to in order to allow dilution. The task is done manually. This exposure is done on pure product (maximum 4.02% of total iodine). Frequency of application is maximum once per day, 5 days per week. The Model 7 for Mixing and Loading – pouring liquids is used. This model figures on the TNsG part II on human exposure to biocidal products and is revised in the HEEG Opinion 1 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, 2008. The indicative values of the HEEG Opinion 1 are stricter than the one of the TNsG Part II. To consider the very worst-case, the values of the HEEG Opinion 1 are used.

MetaSPC8 is classified for skin irritant effects and therefore read across of the dermal absorption to the tested compounds included in the CAR is considered not acceptable. As the total amount of iodine is < 5% (i.e. 4.02%), the default for water based solutions of 50% is used for the dermal exposure assessment of for dilutions containing < 5% a.s. in accordance with the EFSA Guidance on Dermal Absorption (2017).

	Parameters	Value
Tier 1	Dermal absorption	50%
	Respiration rate	0.021 m^3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	5 minutes
	Frequency	Maximum 1 time per day (worst-case)
	Indicative value dermal exposure	101 mg/min
	Indicative value inhalation	0.94 mg/m^3
Tier 2	Indicative value dermal exposure with gloves	1.01 mg/min

Description of Scenario [2] pumping step - metaSPC 8: PT4 Surfaces disinfectants – Iodine

Primary exposure (dermal + inhalation). This task is performed indoors. Dilution step can be done by pumping the pure product from the jerrycan in the container where water will be released to in order to allow dilution. The task is done manually. This exposure is done on pure product (maximum 4.02% of iodine). Frequency of application is maximum once per day 5 days per week. The Model 7 for Mixing and Loading – pumping liquids is used. This model figures on the TNsG part II on human exposure to biocidal products and is revised in the HEEG Opinion 1 on the use of available data and models for the assessment pf the exposure of operators during the loading of products into vessels or systems in industrial scale, 2008. The indicative values of the HEEG Opinion 1 are stricter than the one of the TNsG Part II. To consider the very worst-case, the values of the HEEG Opinion 1 are used.

MetaSPC8 is classified for skin irritant effects and therefore read across to dermal absorption of the tested compounds included in the CAR is considered not acceptable. As the total amount of iodine is < 5% (i.e. 4.02%), the default for water based solutions of 50% is used for the dermal exposure assessment of dilutions containing < 5% a.s. in accordance with the EFSA Guidance on Dermal Absorption (2017).

	Parameters	Value
Tier 1	Dermal absorption	50%
	Respiration rate	0.021 m3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	5 minutes
	Frequency	Maximum 3 times per day (worst-case)
	Indicative value dermal exposure	138 mg/min
	Indicative value inhalation	22 mg/m3
Tier 2	Indicative value dermal exposure with gloves	1.38 mg/min

Description of Scenario [3] spraying step - metaSPC 8: PT4 Surfaces disinfectants - Iodine		
Primary exposure dermal + inhalation (spraying on surfaces). Working solution is sprayed on surfaces with a back pulverisator or an automatic sprayer. This step can take 1 to 3 hours depending on the surface to be disinfected. After a contact time of 15 mintues product is rinsed with water. The disinfection can be done up to 1 time per day, 5 days per week. This exposure is done with diluted product (0.024% of total iodine). According to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 2, the spraying model 1 is used. The potential dermal exposure to the working solution is 181 mg/min for hands outside protective gloves and 10.7 mg/min inside the gloves. The model gives an indicative value of 92 mg/min for body exposure. The first tier should be performed without PPE, meaning without gloves. As the pH of the working solution is superior to 2 and the concentration is below the trigger value for corrosion and irritation, no corrovise or irritant effects are expected, a dermal absorption of 12% is subsequently used to perform a systemic exposure assessment.		
	Parameters[1]	Value
Tier 1	Dermal absorption	12%
	Respiration rate	0.021 m^3/min (equivalent to 1.25 m^3/h; HEEG opinion no. 17)
	Duration time	2 hours (worst-case)
	Frequency	Once per day
	Indicative value dermal exposure (hands)	181 mg/min
	Indicative value dermal exposure (body)	92 mg/min
	Indicative value inhalation	104 mg/m^3
Tier 2	Indicative value dermal exposure with gloves (hands)+ coated coverall	10.7 mg/min, and 90% protection for body exposure

metaSPC 9: PT4 CIP disinfectants in food industry - Iodine

Description of Scenario [1] pouring step - metaSPC 9: PT4 CIP disinfectants in food industry - Iodine

Products included in metaSPC9 are classified with H314; Causes severe skin burns and eye damage. As included in the TAB (version August 2017, TOX14, p55), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.*
Therefore, a qualitative local effects assessment is performed.

As handling does not result in aerosol formation, systemic inhalation exposure does not need to be assessed. However, based on its classification, local risk assessment is performed. This approach for the active is in line with the text included in the TAB as referred to above.

However, metaSPC9 does include the SoC phosphoric acid (based on the presence of an OEL value 1 mg/m3 is) which is is considered volatile (i.e. vapour pressure of 0.03 mmHg (20^{O}C (https://www.cdc.gov/niosh/npg/npgd0506.html), equal to 4 Pa). For a worst case assessment, the product is manually poured from a 5 L container into the apparatus. The air concentration of phosphoric acid during pouring of the product from a 5 L container has been calculated using ConsExpo Web (evaporation from constant surface) and the default parameters in the ConsExpo Cleaning Products Fact Sheet (RIVM report 320104003/2006, p.58) for mixing and loading of a liquid cleaner.

It is not unusual to see air change rates as high as 35 or 50 in a food production cooling system depending upon the circumstances. However, for the assessment the same air changes as considered for hospitals will be taken into account as worst case (1.5 /h, HEADhoc recommendation no. 9).

	Parameters	Value
Tier 1	Adult body weight	60 kg
	Maximum concentration of phosphoric acid	30 % w/w
	Molecular weight	98.0 g/mol
	Density of the product	1 g/ml
	Exposure duration	0.75 min
	Product amount[1]	2500 g
	Room volume (user breathing zone)	1 m^3
	Ventilation rate	1.5/hr (HEADhoc recom. No 9)
	Release area (circular opening of 5 cm diameter for a 5 L container)	20 cm^2
	Emission duration	0.25 min

	Temperature	20 °C
	Mass transfer rate	10 m/hr (new default value in ConsExpo Web)
	Molecular weight matrix[2]	18 g/mol
	Vapour pressure at 20°C	4 Pa
	Inhalation rate	1.25 m^3/hr
	Inhalation absorption	100%
[1] According to ConsExpo Cleaning Products Fact Sheet, the product amount is half the amount of the bottle content. [2] Calculated as the average molecular weight of the rest of the total product (the product minus phosphoric acid)(RIVM Report 2016-0171, p. 31)		

Description of Scenario [2] pumping step - metaSPC 9: PT4 CIP disinfectants in food industry - Iodine

Products included in metaSPC9 are classified with H314; Causes severe skin burns and eye damage. As included in the TAB (version August 2017, TOX14, p55), for oral or dermal exposure no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.*
Therefore, a qualitative local effects assessment is performed.

As handling does not result in aerosol formation, systemic inhalation exposure does not need to be assessed. However, based on its classification, local risk assessment is performed. This approach for the active is in line with the text included in the TAB as referred to above.

However, metaSPC9 does include the SoC phosphoric acid (based on the presence of an OEL value 1 mg/m3 is) which is is considered volatile (i.e. vapour pressure of 0.03 mmHg (20^{O}C (https://www.cdc.gov/niosh/npg/npgd0506.html), equal to 4 Pa). For a worst case assessment, the product is manually poured from a 5 L container into the apparatus. The air concentration of phosphoric acid during pouring of the product from a 5 L container has been calculated using ConsExpo Web (evaporation from constant surface) and the default parameters in the ConsExpo Cleaning Products Fact Sheet (RIVM report 320104003/2006, p.58) for mixing and loading of a liquid cleaner.
The assessment is included in scenario 1 of metaSPC9.

Calculations for Scenarios

metaSPC 7: PT4 Surfaces disinfectants - Iodine

Detailed reports are included Part 8 of IUCLID. The calculation sheet are included in Annex 3.2.

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] pouring	1	5.77E-05 mg/ kg bw/day	3.55E-02 mg/ kg bw/day	No exposure	3.56E-02 mg/ kg bw/day
	2 (gloves)	5.77E-05 mg/ kg bw/day	3.55E-04 mg/ kg bw/day	No exposure	4.12E-04 mg/ kg bw/day
Scenario [2] pumping	1	1.35E-03 mg/ kg bw/day	4.84E-02 mg/ kg bw/day	No exposure	4.98E-02 mg/ kg bw/day
	2 (gloves)	1.35E-03 mg/ kg bw/day	4.84E-04 mg/ kg bw/day	No exposure	1.84E-03 mg/ kg bw/day
Scenario [3] Spraying	1	1.08E-03 mg/ kg bw/day	1.64E-02 mg/ kg bw/day	No exposure	1.75E-02 mg/ kg bw/day
	2 (gloves, coated coverall)	1.08E-03 mg/ kg bw/day	1.19E-03 mg/ kg bw/day	No exposure	2.28E-03 mg/ kg bw/day

Further information and considerations on scenario [1], [2], [3] - metaSPC 7: PT4 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [1] – Mixing and loading Model 7 Pouring	0.0330
Scenario [2] – Mixing and loading Model 7 Pumping	0.7722
Scenario [3] – Spraying	0.0260

Further information and considerations on scenarios [1], [2] – metaSPC 7: PT4 Surfaces disinfectants – Iodine: Local effects of Iodine

Summary table: estimated local exposure from industrial uses						
Exposure scenario	**Hazard category**	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**
Scenario [1] pouring	High	Eye Dam. H318	Industrial	S1 loading product into	Skin Eye	Few minutes or less per day

				spraying device (pouring)	(splashes, hand to eye transfer)	
Scenario [2] pumping	High	Eye Dam. H318	industrial	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day

metaSPC 8: PT4 Surfaces disinfectants - Iodine

The calculation sheet are included in Annex 3.2.

Summary table: estimated exposure from industrial uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] pouring	1	6.61E-05 mg/ kg bw/day	1.69E-01 mg/ kg bw/day	No exposure	1.69E-01 mg/ kg bw/day
	2 (gloves)	6.61E-05 mg/ kg bw/day	1.69E-03 mg/ kg bw/day	No exposure	1.76E-03 mg/ kg bw/day
Scenario [2] pumping	1	1.55E-03 mg/ kg bw/day	2.31E-01 mg/ kg bw/day	No exposure	2.33E-01 mg/ kg bw/day
	2 (gloves)	1.55E-03 mg/ kg bw/day	2.31E-03 mg/ kg bw/day	No exposure	3.86E-03 mg/ kg bw/day
Scenario [3] Spraying	1	1.04E-03 mg/ kg bw/day	1.57E-02 mg/ kg bw/day	No exposure	1.68E-02 mg/ kg bw/day
Scenario [3] Spraying	2 (gloves, coated coverall)	1.04E-03 mg/ kg bw/day	1.15E-03 mg/ kg bw/day	No exposure	2.19E-03 mg/ kg bw/day

Further information and considerations on scenario [3] - metaSPC 8: PT4 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [1] – Mixing and loading Model 7 Pouring	0.038
Scenario [2] – Mixing and loading Model 7 Pumping	0.884
Scenario [3] – Spraying	0.025

Further information and considerations on scenarios [1], [2] – metaSPC8: PT4 Surfaces disinfectants – Iodine: Local effects of Iodine

Summary table: estimated local exposure from industrial uses						
Exposure scenario	**Hazard category**	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**
Scenario [1] pouring	High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	Industrial	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day
Scenario [2] pumping	High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	industrial	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day

metaSPC 9: PT4 CIP disinfectants used in food industry - Iodine

Products included in metaSPC9 are classified with H314; Causes severe skin burns and eye damage. As included in the TAB (version August 2017), no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.*
Therefore, a qualitative local effects assessment is performed.

As handling does not result in aerosol formation, systemic inhalation exposure does not need to be assessed. However, based on its classification, local risk assessment is performed. This approach for the active is in line with the text included in the TAB as referred to above.

However, metaSPC9 does include the SoC phosphoric acid (based on the presence of an OEL value 1 mg/m3 is) which is is considered volatile (i.e. vapour pressure of 0.03 mmHg (20^{O}C (https://www.cdc.gov/niosh/npg/npgd0506.html), equal to 4 Pa). For a worst case assessment, the product is manually poured from a 5 L container into the apparatus. The air concentration of phosphoric acid during pouring of the product from a 5 L container has been calculated using ConsExpo Web (evaporation from constant surface) and the default parameters in the ConsExpo Cleaning Products Fact Sheet (RIVM report 320104003/2006, p.58) for mixing and loading of a liquid cleaner.
The assessment also covers pumping of the product.

Summary table: estimated exposure from professional uses	
Exposure scenario	**Phosphoric acid in air (mg/m³)**
Scenario [1&2] – Mixing and loading ConsExpoweb	Mean event concentration and Peak concentration (TWA 15 min): 8.1E-04

Further information and considerations on scenarios [1], [2] – metaSPC 9: PT4 CIP disinfectants used in food industry – Iodine: Local effects of Iodine

Summary table: estimated local exposure from industrial uses						
Very high	Skin. Corr. 1A H314	Indus-trial	S1 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall
Very high	Skin. Corr. 1A H314	industrial	S2 loading product into the	Skin Eye	Few minutes or less per day	RMM - trained professionals - regular cleaning of

			contained connected to CIP system	(splashes, hand to eye transfer)		equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall

Combined scenarios

metaSPC 7: PT4 Surfaces disinfectants – Iodine

Spraying step is combined with pouring step or pumping step.

Summary table: combined systemic exposure from industrial uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 3] tier 1	1.14E-03	5.19E-03	No exposure	5.30E-02
Scenarios [1, 3] tier 2 – gloves, coated coverall	1.14E-03	1.55E-03	No exposure	2.68E-03
Scenarios [2, 3] tier 1	2.43E-03	6.48E-02	No exposure	6.72E-02
Scenarios [2, 3] tier 2 – gloves, coated coverall	2.43E-03	1.67E-03	No exposure	4.10E-03

metaSPC 8: PT4 Surfaces disinfectants– Iodine

Spraying step is combined with pouring step (scenario 1) or pumping step (scenario 2).

Summary table: combined systemic exposure from industrial uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 3] tier 1	1.10E-03	5.12E-03	No exposure	5.23E-02
Scenarios [1, 3] tier 2 – gloves, coated coverall	1.10E-03	1.51E-03	No exposure	2.60E-03
Scenarios [2, 3] tier 1	2.39E-03	6.41E-02	No exposure	6.65E-02
Scenarios [2, 3] tier 2 – gloves, coated coverall	2.39E-03	1.63E-03	No exposure	4.02E-03

metaSPC 9: PT4 CIP disinfectants used in food industry – Iodine

Combination of exposures via pouring and pumping is considered covered by the local risk assessment.

Professional exposure

Dietary exposure (secondary exposure professionals) is described in the "Dietary exposure".

metaSPC 1: PT3 Concentrated teat disinfectants - Iodine

Description of Scenario [1] dilution (pouring) step - metaSPC 1: PT3 Concentrated teat disinfectants - Iodine		
In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for mixing and loading of concentrated product for dermal exposure, mixing and loading model 4 is used. For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are milked twice a day, however, for robotic milking, cows can be milked three times a day. M*eta*SPC1 and 10 contain concentrated products, and can be used post-milking and the max amount used is 5 ml. Therefore, as worst case the amount needed for one day is: 5ml diluted product x 3 times a day = 15 ml. As the product is used at max 20% (v/v) dilutions, max (15 ml x20% =) 3 ml concentrated product per cow/day is used. Considering 82 cows, this results in a total amount of product per day of 3 ml x 82 cows = 246 ml = 0.25 liter product/day. For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment. In case of loading of electronic sprayer or robotic milking device (for automated spraying) the sucking lance of the electronic sprayeror robotic milking device is inserted in a can containing the diluted product. Therefore, the exposure for the manual scenario is considered worst-case, and therefore used in the exposure calculation. Iodine used for teat disinfection in PT3 is complex-bound to iodophors in the form of triiodide (I_3^-). In aqueous solutions, the bound triiodide releases only minute fractions of free (molecular) iodine (I_2). Free iodine (I_2) immediately reacts with organic matter and forms ionic iodine species such as iodide (I^-) which do not tend to evaporate. Residual free iodine (I_2) in aqueous solutions, if at all present, is considered to lead to negligible exposure towards iodine vapour. The full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box. As iodine in the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed. Exposure from (re)-filling of sprayer with the diluted concentrate is assumed to be covered by the overall M/L step of the concentrate.		
	Parameters	Value

Tier 1	Total iodine (available iodine, iodate and iodide) (*meta* SPC1)	2.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1] dilution (pouring) step - metaSPC 1: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1 mixing and loading of concentrate (*meta*SPC 1) performed once a day.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] – M/L model 4	Tier 1/ none	-	5.00E -04	-	5.00E -04
	Tier 2/ Inside gloves	-	5.00E -05	-	5.00E -05

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2] spraying step - metaSPC 1: PT3 Concentrated teat disinfectants -– Iodine		
In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows 2 times per day - The spraying time per cow/event is 10 seconds - Results in (10 seconds *82 cows) *2 /60 = 27.3 min exposure time		
	Parameters	Value

Tier 1	Total iodine (available iodine, iodate and iodide) in diluted concentrate (*meta*SPC1)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m^3/h (0.021 m^3/min)
	Exposure duration	27.3 min
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [2] - spraying step - metaSPC 1: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2 are provided for 82 animals disinfected after each milking, 2 times per day.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	4.98E-04	1.25E-02	-	1.30E-02
	Tier 2/ Gloves	4.98E -04	3.64E-03	-	4.14E-03

Further information and considerations on scenario [2] - metaSPC 1: PT3 Concentrated teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m^3)**

Scenario [2.] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

The calculation sheets are provided in Appendix 3.2; trigger spray.

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 1: PT3 Concentrated teat disinfectants - Iodine
The disinfectant is expected to have completely dried up and either fallen off or rubbed off the treated teats during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as trigger sprayer after use- metaSPC 1: PT3 Concentrated teat disinfectants - Iodine

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

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

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

	Parameters	Value
	Total iodine (available iodine, iodate and iodide) in RTU (metaSPC1)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as trigger sprayer after use- metaSPC 1: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes a day.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**

Scenario [4.1] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	4.60E-05	-	4.60E -05
	Tier 2/ Gloves	-	4.60E -06	-	4.60E -06

The calculation sheet is included in Annex 3.2; cleaning equipment.

metaSPC 2: PT3 RTU teat disinfectants - Iodine

Description of Scenario [1.1] Mixing and loading preceeding manual spraying step metaSPC 2: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked three times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 2 times a day = 10 ml. Considering 82 cows, this results in a total amount of product per day of 10 ml x 82 cows = 0.82 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment is used.

Iodine used for teat disinfection in PT3 is complex-bound to iodophors in the form of triiodide (I_3^-). In aqueous solutions, the bound triiodide releases only minute fractions of free (molecular) iodine (I_2). Free iodine (I_2) immediately reacts with organic matter and forms ionic iodine species such as iodide (I^-) which do not tend to evaporate. Residual free iodine (I_2) in aqueous solutions, if at all present, is considered to lead to negligible exposure towards iodine vapour. The full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box. As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC2)	0.58%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] mixing and loading preceeding manual spraying step - metaSPC 2: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.1 mixing and loading previous the manual spraying step of RTU (*meta*SPC 2)_performed twice a day.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [1.1] – M/L model 4	Tier 1/ none	-	1.16E-04	-	1.16E-04
	Tier 2/ Inside gloves	-	1.16E-05	-	1.16E-05

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [1.2] Mixing and loading preceeding dipping step or automated spraying step metaSPC 2: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked three times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 3 times a day = 15 ml. Considering 82 cows, this results in a total amount of product per day of 15 ml x 82 cows = 1.23 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

Iodine used for teat disinfection in PT3 is complex-bound to iodophors in the form of triiodide (I_3^-). In aqueous solutions, the bound triiodide releases only minute fractions of free (molecular) iodine (I_2). Free iodine (I_2) immediately reacts with organic matter and forms ionic iodine species such as iodide (I^-) which do not tend to evaporate. Residual free iodine (I_2) in aqueous solutions, if at all present, is considered to lead to negligible exposure towards iodine vapour. The full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box. As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC2)	0.58%
	Dermal penetration	12%
	Body weight	60 kg

	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] mixing and loading preceeding dipping step or automated spraying step - metaSPC 2: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.2 mixing and loading previous the dipping step of RTU (*meta*SPC 2)_performed three time per day.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – M/L model 4	Tier 1/ none	-	2.32E-03	-	2.32E-03
	Tier 2/ Inside gloves	-	2.32E-04	-	2.32E-04

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2.1] spraying step - metaSPC 2: PT3 RTU teat disinfectants – Iodine

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used.
The following assumptions are considered in the calculations:

- The farmer manually milks 82 cows twice a day
- The spraying time per cow/event is 10 seconds

Results in (10 seconds *82 cows) *2 /60 = 27.3 min exposure time

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) in diluted concentrate (*meta*SPC2)	0.58%
	Dermal penetration	12%
	Body weight	60 kg

	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Exposure duration	27.3 min
	No PPE	
Tier 2	Gloves, Non-professionals wearing long-sleeved short and trousers or skirt with shoes	90% protection, 50% protection according to the Biocides Human Health Exposure Methodology (2015)

Calculations for Scenario [2.1] - spraying step - metaSPC 2: PT3 RTU teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2.1 are provided for 82 animals disinfected after each milking, i.e. twice a day

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.1] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	5.78E-04	1.45E-02	-	1.51E-02
	Tier 2/ Gloves, long-sleeved short and trousers or skirt with shoes	5.78E-04	2.68E-03	-	3.26E-03

Further information and considerations on scenario [2] - metaSPC 2: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	6.09E-02

The calculation sheets are provided in Appendix 3.2;trigger spray.

Description of Scenario [2.2] dipping step - metaSPC 2: PT3 RTU teat disinfectants - Iodine
Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17) In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided. Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed.

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 2: PT3 RTU teat disinfectants – Iodine
The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 2: PT3 RTU teat disinfectants - Iodine

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

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

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

	Parameters	Value
	Total iodine (available iodine, iodate and iodide) in RTU (metaSPC2)	0.58%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 2: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes per day

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [4] – 'Loading	Tier 1/ none	-	5.34E-05	-	5.34E -05

liquid, automated or semi-automated’	Tier 2/ Gloves	-	5.34E -06	-	5.34E -06

The calculation sheet is included in Annex 3.2; cleaning equipment.

metaSPC 3: PT3 RTU skin disinfectants - Iodine

Products from metaSPC 3 are used only by professionals in farmhouses on skin of animals in order to avoid cross contamination. 2 modes of use are claimed for this metaSPC:

- disinfection of skin of udder of dairy cows before and after calving, scenario 2.1
- disinfection of skin of udder of sows before and after farrowing, scenario 2.2

Modes of use are detailed in the 2 following description tables.

Description of Scenario [1, 2.1] Disinfection of skin of udder before calving – metaSPC 3 RTU skin disinfectants - Iodine

The ready-to-use disinfectant is applied with a trigger spray on teats of dairy cows once a day: 2 days before calving and 2 days after. Cows give birth once per year. 1 spray is necessary per teat. Considering that 1 spray delivers 1.2 ml of product*, 1.2 ml x 4= 4.8 mL per cow on a daily basis. On the same day, maximum 30% of the herd of dairy cattle can be treated (because there is only 4 days of treatment in total and that cows give birth only once per year). In accordance to the ESD, 82 cows from a 100 cow herd are milkable. Therefore, 100-82=18 cows are considered to give birth and included for the assessment of this scenario.

→ Exposure following the loading step (to load the product in the trigger spray) is estimated with the Mixing and loading model 4 as for products of metaSPC 2.

With products of metaSPC 3: 4.8ml x 18=0.0864L is used. In line with the HEAdhoc recommendations no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), the indicative hand exposure for handling 1L is 0.01 ml/treatment. The products included in this metaSPC is a RTU and contains 1.45% total iodine. Worker is exposed to 18 cows (taking into account skin disinfection) x 0.01 ml/treatment x 1.45%= 2.61E-03 g of total iodine.

With products of metaSPC 2:maximum amount of exposure to the product per day is 82 cows x 0.2 ml/ treatment x 0.58%= 9.5E-02 g of total iodine. Exposure following loading step for teat disinfection with products from metaSPC 2 covers then exposure following loading step for skin disinfection with products from metaSPC 3. Therefore, further investigation is not needed.

→ Exposure following the spraying step:

To disinfect the skin of udder of cows, a trigger spray is used exactly as for teat disinfection by spraying. 4.8 ml x 18 cows x 1.45%= 1.25g of total iodine to which use is potentially exposed.

With products from metaSPC 2, a quantity of 5 mL (with 0.58% of total iodine) is used 3 times per day on 82 cows meaning a potential exposure to 5 ml x 3 times/day x 0.58% x 82 cows =7.13g of total iodine. Exposure following teat disinfection with products from metaSPC 2 covers then the exposure following udder disinfection before calving with products from metaSPC 3. Therefore further investigation is not needed.

Note eCA: that the exposure is covered by metaSPC2, is valid. However, as the assessment for metaSPC2 results in the assignement of PPE, the exposure is assessed for metaSPC3. For the assessment the same values and assumption are used as for metaSPC2. For the duration time of 18 cows, treated once a day for 10 seconds per cow is assumed (i.e. 18*10 sec = 3 min).

All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the professional exposure.

*** CIRLAM Consumption test of Iodine spray & dip products, 03/08/2017, included in IUCLID.**

Description of Scenario [1, 2.2] Disinfection of the udder of sows - metaSPC 3 RTU skin disinfectants - Iodine

The ready-to-use disinfectant is applied with a pulverisator (with a lance) on the udder of sows 1 day before farrowing to avoid cross contamination, once a day and 4 days after farrowing (once a day). max. 20 mL of product is used per animal. Maximum 30% of the herd is treated per day and that a herd contains 132 sows (in accordance to ESD PT3; veterinary hygiene biocidal products 2011). Therefore, 132*30%=40 sows are considered to give birth and included for the assessment of this scenario.

→ Exposure following the loading step (to load the product in the back pulverisator) is estimated with the Mixing and loading model 4 as for products of metaSPC 2.

With products of metaSPC 3: 20 ml x 40sows =0.8L is used. In line with the HEAdhoc recommendations no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), the indicative hand exposure for handling 1L is 0.01 ml/treatment. Worker is exposed to 40 sows x 0.01 ml/treatment x 1.45%=0.006 g of total iodine.

With products of metaSPC 2:worker is exposed to 82 x 0.2 x 3 x 0.58%=0.285 g of total iodine. Exposure following loading step for teat disinfection with products from metaSPC 2 covers then exposure following loading step for udder disinfection of sows with products from metaSPC 3. Therefore, further investigation is not needed.

→ Exposure following the spraying step

With products of metaSPC 3: maximum 20mLx40 sows*1.45%=11.6g of total iodine can be used per day.

With products of metaSPC 8: worker is exposed to 0.56*40/1000*2200 (area of stables in accordance to ESD PT3, 2011)=49.28 g of iodine. Exposure following stable disinfection with products from metaSPC 8 covers then the exposure following udder disinfection of sows before farrowing with products from metaSPC 3.

Therefore further investigation is not needed.

Note eCA: that the mixing and loading exposure is covered by metaSPC2, is valid. However, as the spraying exposure is considered more comparable to trigger spray exposure that for the exposure for metaSPC8 uses, this is considered not valid. Therefore, the same model as for spraying teat disinfection is used. For the assessment, 10 seconds for treatment per animal is assumed. 30% of the herd is expected for farrowing, therefore 40 sow are treated once per day. Resulting in 40 sows*10 sec = 400 seconds, equal to 6.7min.
Because the assessment for metaSPC8 results in the assignement of PPE, the exposure is assessed for metaSPC3. For the assessment the same models and assumption are used as for teat disinfection.
Furthermore, cleaning of the spraying equipment needs to be included for the exposure of the professional user. For the assessment the same values and assumptions are used as included for teat disinfection as included for metaSPC2.

All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the combined professional exposure.

metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine

Regarding teat disinfection

Description of Scenario [1.1] Mixing and loading preceeding manual spraying step metaSPC 4: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally two times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 2 times a day = 10 ml.
Considering 82 cows, this results in a total amount of product per day of 10 ml x 82 cows = 0.82 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC4)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] mixing and loading preceeding manual spraying step - metaSPC 4: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.1 mixing and loading of RTU (*meta*SPC 4) performed twice a day.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [1.1] – M/L model 4	Tier 1/ none	-	1.00E-04	-	1.00E-04
	Tier 2/ Inside gloves	-	1.00E-05	-	1.00E-05

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [1.2] Mixing and loading preceeding dipping step or automated spraying step metaSPC 4: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally three times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 3 times a day = 15 ml.
Considering 82 cows, this results in a total amount of product per day of 15 ml x 82 cows = 1.23 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC4)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	No PPE	

Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] mixing and loading preceeding dipping step or authomated spraying step- metaSPC 4: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.2 mixing and loading of RTU (*meta*SPC 4) performed three times a day.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – M/L model 4	Tier 1/ none	-	2.00E-03	-	2.00E-03
	Tier 2/ Inside gloves	-	2.00E-04	-	2.00E-04

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2.1] spraying step - metaSPC 4: PT3 RTU teat disinfectants – Iodine		
In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows twice a day - The spraying time per cow/event is 10 seconds Results in (10 seconds *82 cows) *2 /60 = 27.3 min exposure time		
	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) in diluted concentrate (*meta*SPC4)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m³/h (0.021 m³/min)
	Exposure duration	27.3 min

	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [2.1] - spraying step - metaSPC 4: PT3 RTU teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2.1 are provided for 82 animals disinfected after each milking, i.e. twice a day

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.1] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	4.98E-04	1.25E-02	-	1.30E-02
	Tier 2/ Inside gloves (acc. to model)	4.98E -04	3.64E-03	-	4.14E-03

Further information and considerations on scenario [2.1] - metaSPC 4: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

The calculation sheets are provided in Appendix 3.2;trigger spray.

Description of Scenario [2.2] dipping step - metaSPC 4: PT3 RTU teat disinfectants - Iodine

Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17)

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided.

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 4: PT3 RTU teat disinfectants – Iodine

The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.

Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure.
This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 4: PT3 RTU teat disinfectants - Iodine

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

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

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

	Parameters	Value
	Total iodine (available iodine, iodate and iodide) in RTU (metaSPC4)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 4: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes per day

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [4.1] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	4.60E-05	-	4.60E -05
	Tier 2/ Gloves	-	4.60E -06	-	4.60E -06

The calculation sheet is included in Annex 3.2; cleaning equipment.

Regarding the skin disinfection

Regarding the skin disinfection:
Modes of use for skin disinfection are the same as for skin disinfection in metaSPC 3. Exposures following occasional uses of products from metaSPC 4 (up to 0.5% of total iodine) are covered by exposure to products from metaSPC 3 (up to 1.45% of total iodine) which are covered by the ones from metaSPC 2 (up to 0.58% of total iodine). Therefore there is no need for further investigation.

Note eCA: that the exposure is covered by metaSPC3, is valid. However, as the assessment for metaSPC3 results in the assignement of PPE, the exposure is assessed for metaSPC4 to check if this would result in the same PPE, using the same models and assumptions as for metaSPC3.
All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the combined professional exposure.

metaSPC 5: RTU teat disinfectant – PVP-Iodine

Exposures following use of teat disinfectants from metaSPC 5 (total iodine is equal to 0.58%) are covered by the ones following use of teat disinfectants from metaSPC 2 (up to 0.3% of iodine, total iodine is equal to 0.58%). Therefore, there is no need for further investigation.

Comment eCA; calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2 in the embedded document for professional exposure. The assessments results in the same RMM as for metaSPC2.

metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine

Comment eCA;due to changes in the assessment evaluation, this metaSPC is no longer covered by other metaSPCs. The exposure to iodine due to the use of products included in metaSPC6 is assessed, using the same models and assumptions as for metaSPC3.

All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the combined professional exposure.

metaSPC 7: PT3 Surfaces disinfectants - Iodine

Pouring and pumping steps are the same as for PT4-use (industrial users).

Description of Scenario [3] spraying step - metaSPC 7: PT3 Surfaces disinfectants - Iodine		
Primary exposure dermal + inhalation (spraying on surfaces). working solution is sprayed on surfaces with a back pulverisator or an automatic sprayer. According to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 2, the spraying model 2 is used. The potential dermal exposure to the working solution is 273 mg/min for hands outside protective gloves and 7.8 mg/min inside the gloves. The model gives an indicative value of 222 mg/min for body exposure. The first tier should be performed without PPE, meaning without gloves. Doors and vents are fully open during application and after. The contact time is 60 minutes. The product dries on surfaces. Only then, animals can re-enter in the housing. The disinfection can be done up to 1 time per day. Frequency of application is maximum 13 times per year for ducks according to the ESD for PT3 for veterinary hygiene biocidal products. This exposure is done with diluted product. The metaSPC contains a range of 1.8-2.49% available iodine and the intended use instructions includes a max. 0.035% in-use available iodine concentration. Considering the worst case, 1.8% needs to be diluted to 0.035% is a 1/0.03=51.4 fold dilution, resulting in a max. total iodine of 0.059%.		
	Parameters[1]	Value
Tier 1	Dermal absorption	12%
	Respiration rate	1.25 m3/h
	Duration time	2 hours (worst-case)
	Indicative value dermal exposure (hands)	273 mg/min
	Indicative value dermal exposure (body)	222 mg/min
	Indicative value inhalation	76 mg/m3
Tier 2	Indicative value dermal exposure with gloves (hands) and coveral	Gloves (hands): 7.8 mg/min Coated coverall: 90% protection Impermeable coverall: 95% protection

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3] Spraying	1	1.87E-03 mg/ kg bw/day	7.01E-02 mg/ kg bw/day	No exposure	7.20E-02 mg/ kg bw/day
	2 (gloves, coated coverall	1.87E-03 mg/ kg bw/day	4.25E-03 mg/ kg bw/day	No exposure	6.12E-03 mg/ kg bw/day
	2 (gloves, impermeable coverall	1.87E-03 mg/ kg bw/day	2.68E-03 mg/ kg bw/day	No exposure	4.55E-03 mg/ kg bw/day

The calculation sheet are included in Annex 3.2.

Further information and considerations on scenario [1], [2], [3] - metaSPC 7: PT3 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [1] – Mixing and loading Model 7 Pouring	0.0330
Scenario [2] – Mixing and loading Model 7 Pumping	0.7722
Scenario [3] – Spraying	0.0448

metaSPC 8: PT3 Surfaces disinfectants - Iodine

Pouring and pumping steps are the same as for PT4-use (industrial users).

Description of Scenario [3] spraying step - metaSPC 8: PT3 Surfaces disinfectants - Iodine		
Primary exposure dermal + inhalation (spraying pn surfaces). working solution is sprayed on surfaces with a back pulverisator or an automatic sprayer. According to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure Methods and models to assess exposure to biocidal products in different product types Version 2, the spraying model 2 is used. The potential dermal exposure to the working solution is 273 mg/min for hands outside protective gloves and 7.8 mg/min inside the gloves. The model gives an indicative value of 222 mg/min for body exposure. The first tier should be performed without PPE, meaning without gloves. Doors and vents are fully open during application and after. The contact time is 60 minutes. The product dries on surfaces. Only then, animals can re-enter in the housing. The disinfection can be done up to 1 time per day. Frequency of application is maximum 13 times per year for ducks according to the ESD for PT3 for veterinary hygiene biocidal products. . The metaSPC contains a range of 2.5-3% available iodine and the intended use instructions includes a max. 0.035% in-use available iodine concentration. Considering the worst case, 2.5% needs to be diluted to 0.035% is a 2.5/0.035=71.4 fold dilution, resulting in a max. total iodine of 0.056%.		
	Parameters[1]	Value
Tier 1	Dermal absorption	12%
	Respiration rate	1.25 m3/h
	Duration time	2 hours (worst-case)
	Indicative value dermal exposure (hands)	273 mg/min
	Indicative value inhalation	76 mg/m3
Tier 2	Indicative value dermal exposure with gloves (hands) and coveral	Gloves (hands): 7.8 mg/min Coated coverall: 90% protection Impermeable coverall: 95% protection

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3] Spraying	1	1.77E-03 mg/ kg bw/day	6.65E-02 mg/ kg bw/day	No exposure	6.83E-02 mg/ kg bw/day
	2 (gloves, coated coverall	1.77E-03 mg/ kg bw/day	4.03E-03 mg/ kg bw/day	No exposure	5.80E-03 mg/ kg bw/day

	2 (gloves, impermeable coverall	1.77E-03 mg/ kg bw/day	2.54E-03 mg/ kg bw/day	No exposure	4.31E-03 mg/ kg bw/day

The calculation sheet are included in Annex 3.2.

Further information and considerations on scenario [3] - metaSPC 8: PT3 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [3] – Spraying	0.0426

metaSPC 9: PT4 CIP disinfectants for milking parlours - Iodine

Pouring and pumping steps are the same as for PT4-use in the food industry (industrial users). Only the frequency is different for milking parlours then for the food industry. In farms disinfection of the milk installation is done twice a day and disinfection of milk tank is done once every three days according to the environmental exposure scenario in "JRC Scientific and Technical Reports. Emission Scenario Document for Product Type 4 Disinfectants used in food and feed areas, 2011". Worst-case number of dilution per day is then 3 times per day. However, this does not change the exposure per day.

metaSPC 1.10: PT3 Concentrated teat disinfectants – Iodine

Description of Scenario [1] dilution (pouring) step - metaSPC10: PT3 Concentrated teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Manually, cows are milked twice a day, however, for robotic milking, cows can be milked three times a day. *meta*SPC 1 and 10 contain concentrated products, and can be used post-milking and the max amount used is 5 ml. Therefore, as worst case the amount needed for one day is: 5ml diluted product x 3 times a day = 15 ml.
As the product is used at max 11% (v/v) dilutions (resulting in a max. 0.46% total iodine in the in-use dilution), max (15 ml x11% =) 1.65ml concentrated product per cow/day is used. Considering 82 cows, this results in a total amount of product per day of 1.65 ml x 82 cows = 135.3 ml = 0.14 liter product/day.
For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment.

In case of loading of electronic sprayer or robotic milking device (for automated spraying) the sucking lance of the electronic sprayer, automated dipping/foaming-system or robotic milking device is inserted in a can containing the RTU product. Therefore, the exposure for the manual scenario is considered worst-case, and therefore used in the exposure calculation.

As iodine in the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

Exposure from (re)-filling of dipping cups or sprayer with the diluted concentrate is assumed to be covered by the overall M/L step of the concentrate.

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta* SPC10)	4.3%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1] dilution (pouring) step - metaSPC 10: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1 mixing and loading of concentrate (*meta*SPC 10).

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1] – M/L model 4	Tier 1/ none	-	8.60E-04	-	8.60E-04
	Tier 2/ Inside gloves	-	8.60E-05	-	8.60E-05

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2] spraying step - metaSPC 10: PT3 Concentrated teat disinfectants – Iodine

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used.
The following assumptions are considered in the calculations:

- The farmer milks 82 cows twice a day
- The spraying time per cow/event is 10 seconds
- Results in (10 seconds *82 cows) *2/60 = 27.3 min exposure time

	Parameters	Value
Tier 1	Total iodine (available iodine and iodide) in diluted concentrate (*meta*SPC10, 11% v/v)	0.46%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m^3/h (0.021 m^3/min)
	Exposure duration	27.3 min

	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [2] - spraying step - metaSPC 10: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2 are provided for 82 animals disinfected after each milking, i.e. 2 times per day in the worst-case.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	4.58E-04	1.15E-02	-	1.20E-02
	Tier 2/ Gloves	4.58E -04	3.35E-03	-	3.81E-03

Further information and considerations on scenario [2] - metaSPC 10: PT3 Concentrated teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2] – Consumer spraying and dusting model 2, Hand-held trigger spray	4.83E-02

The calculation sheets are provided in Appendix 3.2-I; trigger spray.

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 10: PT3 Concentrated teat disinfectants - Iodine

The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.

Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure.
This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 10: PT3 Concentrated teat disinfectants - Iodine

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

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

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

	Parameters	Value
	Total iodine (available iodine and iodide) in RTU (metaSPC10)	0.5%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 10: PT3 Concentrated teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes a day.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [4.1] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	4.23E-05*	-	4.23E -05
	Tier 2/ Gloves	-	4.23E -06	-	4.23E -06

The calculation sheet is included in Annex 3.2; cleaning equipment.

metaSPC 11: RTU teat disinfectant – Iodine

Description of Scenario [1.1] Mixing and loading preceeding manual spraying step metaSPC 11: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally two times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 2 times a day = 10 ml.
Considering 82 cows, this results in a total amount of product per day of 10 ml x 82 cows = 0.82 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC11)	0.44%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event
	No PPE	

Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] mixing and loading preceeding manual spraying step - metaSPC 11: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.1 mixing and loading of RTU (*meta*SPC 11) performed twice a day, considering the rtu product containing 0.44% total iodine.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1] – M/L model 4	Tier 1/ none	-	8.80E-05	-	8.80E-05
	Tier 2/ Inside gloves	-	8.80E-06	-	8.80E-06

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [1.2] Mixing and loading preceeding dipping step or automated spraying step metaSPC 11: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally three times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 3 times a day = 15 ml.
Considering 82 cows, this results in a total amount of product per day of 15 ml x 82 cows = 1.23 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC11)	0.44%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] mixing and loading preceeding dipping step or automated spraying step- metaSPC 11: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.2 mixing and loading of RTU (*meta*SPC 11) performed three times per day, considering the rtu product containing 0.44% total iodine.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – M/L model 4	Tier 1/ none	-	1.76E-03	-	1.76E-03
	Tier 2/ Inside gloves	-	1.76E-04	-	1.76E-04

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2.1] spraying step - metaSPC 11: PT3 RTU teat disinfectants – Iodine		
In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows twice a day - The spraying time per cow/event is 10 seconds Results in (10 seconds *82 cows) *2 /60 = 27.3 min exposure time		
	Parameters	Value

Tier 1	Total iodine (available iodine, iodate and iodide) in diluted concentrate (*meta*SPC11)	0.44%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m^3/h (0.021 m^3/min)
	Exposure duration	27.3 min
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [2.1] - spraying step - metaSPC 11: PT3 RTU teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2.1 are provided for 82 animals disinfected after each milking, i.e. twice a day

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.1] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	4.38E-04	1.10E-02	-	1.15E-02
	Tier 2/ Gloves	4.38E -04	3.20E-03	-	3.64E-03

Further information and considerations on scenario [2.1] - metaSPC 11: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m^3)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	4.62E-02

The calculation sheets are provided in Appendix 3.2; trigger spray.

Description of Scenario [2.2] dipping step - metaSPC 11: PT3 RTU teat disinfectants - Iodine
Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17) In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided. Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 11: PT3 RTU teat disinfectants – Iodine
The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible. Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure. This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 11: PT3 RTU teat disinfectants - Iodine

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

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

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

	Parameters	Value
	Total iodine (available iodine, iodate and iodide) in RTU (metaSPC11)	0.44%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 11: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes per day

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [4] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	4.05E-05	-	4.05E -05
	Tier 2/ Gloves	-	4.05E -06	-	4.05E -06

The calculation sheet is included in Annex 3.2; cleaning equipment.

metaSPC 12: RTU teat disinfectant – Iodine

Description of Scenario [1.1] Mixing and loading preceeding manual spraying step metaSPC 12: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally two times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 2 times a day = 10 ml.
Considering 82 cows, this results in a total amount of product per day of 10 ml x 82 cows = 0.82 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 1 L is 0.01 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC12)	0.60%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.01 ml/event

	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.1] mixing and loading preceeding manual spraying step - metaSPC 12: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.1 mixing and loading of RTU (*meta*SPC 12) performed twice a day, considering the rtu product containing 0.60% total iodine.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1] – M/L model 4	Tier 1/ none	-	1.20E-04	-	1.20E-04
	Tier 2/ Inside gloves	-	1.20E-05	-	1.20E-05

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [1.2] Mixing and loading preceeeding dipping step or automated spraying step metaSPC 12: PT3 RTU teat disinfectants - Iodine

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

For the dermal exposure, the total amount of the required solution that is needed per day is of importance. Cows are milked maximally three times per day, treated post-milking, therefore, as worst case the amount needed for one day is: 5ml product x 3 times a day = 15 ml.
Considering 82 cows, this results in a total amount of product per day of 15 ml x 82 cows = 1.23 L product/day.
For mixing and loading model 4, the indicative hand exposure for handling 5 L is 0.2 ml/treatment is used.

As iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

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

	Parameters	Value
Tier 1	Total iodine (available iodine, iodate and iodide) (*meta*SPC12)	0.60%
	Dermal penetration	12%
	Body weight	60 kg
	indicative dermal exposure value (mixing and loading model 4)	0.2 ml/event
	No PPE	
Tier 2	Gloves	90% protection

Calculations for Scenario [1.2] mixing and loading preceeding dipping step or automated spraying step- metaSPC 12: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 1.2 mixing and loading of RTU (*meta*SPC 12) performed three times per day, considering the rtu product containing 0.60% total iodine.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.2] – M/L model 4	Tier 1/ none	-	2.40E-03	-	2.40E-03
	Tier 2/ Inside gloves	-	2.40E-04	-	2.40E-04

The calculation sheet is included in Annex 3.2; mixing and loading model 4.

Description of Scenario [2.1] spraying step - metaSPC 12: PT3 RTU teat disinfectants – Iodine		
In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by spraying (both manual trigger spraying and electronic spraying (not with robot)) Hand-held trigger spray model (consumer product spraying and dusting model 2, Biocides Human Health Exposure Methodology) is used. The following assumptions are considered in the calculations: - The farmer milks 82 cows twice a day - The spraying time per cow/event is 10 seconds Results in (10 seconds *82 cows) *2 /60 = 27.3 min exposure time		
	Parameters	Value

Tier 1	Total iodine (available iodine, iodate and iodide) in diluted concentrate (*meta*SPC11)	0.60%
	Dermal penetration	12%
	Body weight	60 kg
	Inhalation rate (short- and long-term; acc. to HEEG opinion "Default human factor values for use in exposure assessments for biocidal products", 2013)	1.25 m^3/h (0.021 m^3/min)
	Exposure duration	27.3 min
	No PPE	
Tier 2	Gloves Non-professionals wearing long-sleeved short and trousers or skirt with shoes	90% protection 50% protection according to the Biocides Human Health Exposure Methodology (2015)

Calculations for Scenario [2.1] - spraying step - metaSPC 12: PT3 RTU teat disinfectants - Iodine

In the following, the results of the exposure calculations of scenario 2.1 are provided for 82 animals disinfected after each milking, i.e. twice a day

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2.1] – Consumer spraying and dusting Model 2. Hand-held trigger spray	Tier 1/ none	5.98E-04	1.50E-02	-	1.56E-02
	Tier 2/ Gloves	5.98E-04	2.77E-03	-	3.37E-03

Further information and considerations on scenario [2.1] - metaSPC 12: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses

Exposure scenario	Iodine in air inhaled (mg/m³)
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	6.30E-02

The calculation sheets are provided in Appendix 3.2; trigger spray.

Description of Scenario [2.2] dipping step - metaSPC 12: PT3 RTU teat disinfectants - Iodine

Dipping model 4, which was used in the CAR for calculating exposure from dipping, is not considered relevant for estimating this exposure scenario in HEAdhoc recommendation 6, as this model is derived from "semiautomatic dipping in open vats (fishing nets)". This task cannot really be compared to manual disinfection of cow teats with a dipping cup (HEAdhoc recommendation 6, note 17)

In line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017), for application by dipping indicate the the exposure during the use of dipping cups is covered by the dermal exposure as calculated by the scenario of mixing and loading. Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocidal product or treated teat is avoided.

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

Description of Scenario [3] Cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment - metaSPC 12: PT3 RTU teat disinfectants – Iodine

The disinfectant is expected to have completely dried up and either fallen off or rubbed off during the time span between treatment and cleaning. Therefore, any exposure to remains of the disinfectant on the teats is considered to be negligible.

Generally dry disposable paper tissues are used. Since the residues (if any) are dry and the tissue is dry as well and disposed after each animal, there is definitely no relevant exposure.
This conclusion is in line with HEAdhoc recommendation no. 13: Exposure Assessment of Teat Disinfection Products for Veterinary Hygiene (PT3) (Agreed at the Human Health Working Group I on 19 January 2017) for this exposure scenario.

Description of Scenario [4] - Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 12: PT3 RTU teat disinfectants - Iodine

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

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

Additionally, as iodine is the product is complex-bound in the formulation, no evaporation is expected and therefore no inhalation exposure is assessed (see full expert statement "2018-01-29" is provided in IUCLID 8 "Toxicological profile for humans and animals" in the box "attachments of the information panel box).

	Parameters	Value
	Total iodine (available iodine, iodate and iodide) in RTU (metaSPC12)	0.60%
	Dermal penetration	12%
	Body weight	60 kg
	indicative value of RISKOFDERM 'Loading liquid, automated or semi-automated'	0.92 mg/min
	Exposure duration	5 min per day
	No PPE	0% protection
Tier 2	Gloves	90% protection

Calculations for Scenario [4] – Cleaning of equipment such as dip cups, trigger sprayer after use- metaSPC 12: PT3 RTU teat disinfectants - Iodine

In the following, the results of the calculations are provided for scenario 4 performed 5 minutes per day

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake	Estimated total uptake (mg/kg bw/d)
Scenario [4] – 'Loading liquid, automated or semi-automated'	Tier 1/ none	-	5.52E-05	-	5.52E-05
	Tier 2/ Gloves	-	5.52E-06	-	5.52E-06

The calculation sheet is included in Annex 3.2; cleaning equipment.

Calculations for Scenarios

metaSPC 1: PT3 concentrated teat disinfectants – Iodine

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13. The table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1	-	5.00E -04	-	5.00E -04
Scenario [1]	2 (gloves)	-	5.00E -05	-	5.00E -05
Scenario [2]	1	4.98E-04	1.25E-02	-	1.30E-02
Scenario [2]	2 (gloves)	4.98E -04	3.64E-03	-	4.14E-03
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	4.60E-05	-	4.60E -05
Scenario [4]	2 (gloves)	-	4.60E -06	-	4.60E -06

Further information and considerations on scenario [2] - metaSPC 1: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

metaSPC 2: PT3 RTU teat disinfectants – Iodine

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13. The table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1]	1	-	1.16E-04	-	1.16E-04
Scenario [1.1]	2/Gloves	-	1.16E-05	-	1.16E-05
Scenario [1.2]	1	-	2.32E-03	-	2.32E-03
Scenario [1.2]	2/Gloves	-	2.32E-04	-	2.32E-04
Scenario [2.1]	1	5.78E-04	1.45E-02	-	1.51E-02
	2/Gloves	5.78E-04	2.68E-03	-	3.26E-03
Scenario [2.2]	Exposure is considered covered by the mixing and loading scenario.				
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	5.34E-05	-	5.34E-05
	2/Gloves	-	5.34E-06	-	5.34E-06

Further information and considerations on scenario [2] - metaSPC 2: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	6.09E-02

metaSPC 3: PT3 RTU skin disinfectants – Iodine

Exposures following occasional uses of products from metaSPC 3 on udders of dairy cowsand on udders of sows are covered by exposure to products from metaSPC2 and metaSPC 8. Therefore there is no need for further investigation.

Note eCA: that the exposure is covered by metaSPC2, is valid. However, as the assessment for metaSPC2 results in the assignement of PPE, the exposure is assessed for metaSPC3. Furthermore, as the input for parameters are different for the use on cows and sows, separate risk assessments are performed, respectively scenario 2.1 and 2.2.

Morover, mixing and loading and cleaning of spraying equipment is assessed in the same manner as performed for teat disinfection which is in accordance to HEAdhoc 13.

All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the professional exposure.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [1]	1	-	2.90E-04	-	2.90E-04
Scenario [1]	2/Gloves	-	2.90E-05	-	2.90E-05
Scenario [2.1]	1	1.59E-04	3.98E-03	-	4.14E-03
	2/Gloves	1.59E-04	1.16E-03	-	1.32E-03
Scenario [2.2]	1	3.54E-04	8.90E-03	-	9.25E-03
	2/Gloves	3.54E-04	2.59E-03	-	2.94E-03
Scenario [3]	1	-	1.33E-04	-	1.33E-04
	2/Gloves	-	1.33E-05	-	1.33E-05

Further information and considerations on scenario [2] - metaSPC 3: PT3 RTU skin disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1 and 2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	1.52E-01

metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine

Exposures following use of teat disinfectants from metaSPC 4 (up to 0.5% of total iodine)

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13 table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1]	1	-	1.00^{E}-04	-	1.00^{E}-04
Scenario [1.1]	2/Gloves	-	1.00^{E}-05	-	1.00^{E}-05
Scenario [1.2]	1	-	2.00E-03	-	2.00E-03
Scenario [1.2]	2/Gloves	-	2.00E-04	-	2.00E-04
Scenario [2.1]	1	4.98E-04	1.25E-02	-	1.30E-02
	2/Gloves	4.98E -04	3.64E-03	-	4.14E-03
Scenario [2.2]	Exposure is considered covered by the mixing and loading scenario.				
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	4.60E -05	-	4.60E-05
	2/Gloves	-	4.60E -06	-	4.60E -06

Further information and considerations on scenario [2] - metaSPC 4: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

Exposures following occasional uses of products from metaSPC 4 on udders of dairy cows, and on udder of sows are covered by exposure to products from metaSPC 2 (up to 0.78% of total iodine). Therefore there is no need for further investigation.

Exposures following use of skin disinfectants from metaSPC 4 (up to 0.5% of total iodine)

Note eCA: that the exposure is covered by metaSPC3, is valid. However, as the assessment for metaSPC4 results in the assignement of reduced PPE compared to metaSPC3, a table including results from the calculations is included below.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [1]	1	-	1.00E-04	-	1.00E-04
Scenario [1]	2/Gloves	-	1.00E-05	-	1.00E-05
Scenario [2.1]	1	5.47E-05	1.37E-03	-	1.43E-03
	2/Gloves	5.47E-05	3.99E-04	-	4.54E-04
Scenario [2.2]	1	1.22E-04	3.07E-03	-	3.19E-03
	2/Gloves	1.22E-04	8.92E-04	-	1.01E-03
Scenario [3]	1	-	4.60E-05	-	4.60E-05
	2/Gloves	-	4.60E-06	-	4.60E-06

Further information and considerations on scenario [2] - metaSPC 4: PT3 RTU skin disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses

Exposure scenario	Iodine in air inhaled (mg/m³)
Scenario [2.1 and 2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	5.25E-02

metaSPC 5: RTU teat disinfectant – PVP-Iodine

Exposures following use of teat disinfectants from metaSPC 5 (maximum 0.58% total iodine) are covered by the ones following use of teat disinfectants from metaSPC 2 (maximum of 0.58% of total iodine). Therefore, there is no need for further investigation.

Comment eCA; calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2 in the embedded document for professional exposure. The assessments results in the same RMM as for metaSPC2.

metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine

Comment eCA;due to changes in the assessment evaluation, this metaSPC is no longer covered by other metaSPCs. The exposure to iodine due to the use of products included in metaSPC6 is assessed, using the same models and assumptions as for metaSPC3.

All calculations are included in annex 3.2; mixing and loading model 4, and in trigger spray, cleaning equipment and in the professional exposure.

Summary table: estimated exposure from professional uses

Exposure scenario	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenario [1]	1	-	3.60E-04	-	3.60E-04
Scenario [1]	2/Gloves	-	3.60E-05	-	3.60E-05
Scenario [2.1]	1	1.97E-04	4.95E-03	-	5.15E-03
	2/Gloves	1.97E-04	1.44E-03	-	1.64E-03
Scenario [2.2]	1	4.40E-04	1.10E-02	-	1.15E-02
	2/Gloves	4.40E-04	3.21E-03	-	3.65E-03
Scenario [3]	1	-	1.66E-04	-	1.66E-04
	2/Gloves	-	1.66E-05	-	1.66E-05

Further information and considerations on scenario [2] - metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1 and 2.2] – Consumer spraying and dusting model 2, Hand-held trigger spray	1.89E-01

metaSPC 7: PT3 Concentrated surfaces disinfectants – Iodine

Details on calculations are presented in the Human Health risk assessment for PT3 use: disinfection of animal housings metaSPC 7 based on iodine- CIRLAM Project 49TSPC 1.7062015 version 1 done by CIRLAM Laboratory (14 October 2015) and annexed in Part 8 of the IUCLID 5.6.0. The calculation sheet are included in Annex 3.2.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] pouring	1	5.77E-05 mg/ kg bw/day	3.55E-02 mg/ kg bw/day	No exposure	3.55E-02 mg/ kg bw/day
Scenario [1] pouring	2 (gloves)	5.77E-05 mg/ kg bw/day	3.55E-04 mg/ kg bw/day	No exposure	4.12E-04 mg/ kg bw/day
Scenario [2] pumping	1	1.35E-03 mg/ kg bw/day	4.84E-02 mg/ kg bw/day	No exposure	4.98E-02 mg/ kg bw/day
Scenario [2] pumping	2 (gloves)	1.35E-03 mg/ kg bw/day	4.84E-04 mg/ kg bw/day	No exposure	1.84E-03 mg/ kg bw/day
Scenario [3] spraying	1	1.87E-03 mg/ kg bw/day	7.01E-02 mg/ kg bw/day	No exposure	7.20E-02 mg/ kg bw/day
Scenario [3] spraying	2 (gloves, and coated coverall)	1.87E-03 mg/ kg bw/day	4.25E-03 mg/ kg bw/day	No exposure	6.12E-03 mg/ kg bw/day
Scenario [3] spraying	2 (gloves, and impermeable coverall)	1.87E-03 mg/ kg bw/day	2.68E-03 mg/ kg bw/day	No exposure	4.55E-03 mg/ kg bw/day

Further information and considerations on scenario [1], [2], [3] - metaSPC 7: PT3 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [1] – Mixing and loading Model 7 Pouring	0.0330
Scenario [2] – Mixing and loading Model 7 Pumping	0.7722
Scenario [3] – Spraying	0.0448

Further information and considerations on scenarios [1], [2] – metaSPC 7: PT3 Surfaces disinfectants – Iodine: Local effects of Iodine

Summary table: estimated local exposure from industrial uses						
Exposure scenario	**Hazard category**	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**
Scenario [1] pouring	High	Eye Dam. H318	Professional	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day
Scenario [2] pumping	High	Eye Dam. H318	Professional	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day

metaSPC 8: PT3 Concentrated surfaces disinfectants – Iodine

The calculation sheets are included in Annex 3.2.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1] pouring	1	6.61E-05 mg/ kg bw/day	1.69E-01 mg/ kg bw/day	No exposure	1.69E-01 mg/ kg bw/day
	2 (gloves)	6.61E-05 mg/ kg bw/day	1.69E-03 mg/ kg bw/day	No exposure	1.76E-03 mg/ kg bw/day
Scenario [2] pumping	1	1.55E-03 mg/ kg bw/day	2.31E-01 mg/ kg bw/day	No exposure	2.33E-01 mg/ kg bw/day
	2 (gloves)	1.55E-03 mg/ kg bw/day	2.31E-03 mg/ kg bw/day	No exposure	3.86E-03 mg/ kg bw/day
Scenario [3] spraying	1	1.77E-03 mg/ kg bw/day	6.65E-02 mg/ kg bw/day	No exposure	6.83E-02 mg/ kg bw/day

Scenario [3] spraying	2 (gloves & coated coverall)	1.77E-03 mg/ kg bw/day	4.03E-03 mg/ kg bw/day	No exposure	5.80E-03 mg/ kg bw/day
Scenario [3] spraying	2 (gloves & impermeable coverall)	1.77E-03 mg/ kg bw/day	2.54E-03 mg/kg bw/day	No exposure	4.31E-03 mg/kg bw/day

Further information and considerations on scenario [3] - metaSPC 8: PT3 Surfaces disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [1] – Mixing and loading Model 7 Pouring	0.038
Scenario [2] – Mixing and loading Model 7 Pumping	0.884
Scenario [3] – Spraying	0.0426

Further information and considerations on scenarios [1], [2] – metaSPC8: PT3 Surfaces disinfectants – Iodine: Local effects of Iodine

Summary table: estimated local exposure from industrial uses						
Exposure scenario	**Hazard category**	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**
Scenario [1] pouring	High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	Industrial	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day
Scenario [2] pumping	High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	industrial	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day

metaSPC 9: PT4 CIP disinfectants for milking parlours – Iodine

Products included in metaSPC9 are classified with H314; Causes severe skin burns and eye damage. As included in the TAB (version August 2017), no systemic risk assessment needs to be performed, based on the following argumentation: *The use of appropriate personal protective equipment and risk mitigation measures will always be required for*

corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.
Therefore, a qualitative local effects assessment is performed.

As handling does not result in aerosol formation, systemic inhalation exposure does not need to be assessed. However, based on its classification, local risk assessment is performed.

Further information and considerations on scenarios [1], [2] – metaSPC 9: PT4 CIP disinfectants used in milking parlour – Iodine: Local effects of Iodine

Summary table: estimated local exposure from use in milking parlour						
Very high	Skin. Corr. 1A H314	Professional	S1 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall
Very high	Skin. Corr. 1A H314	Professional	S2 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall

metaSPC 10: PT3 Concentrated teat disinfectants – Iodine

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13 table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]	1	-	8.60E-04	-	8.60E-04
	2 (gloves)	-	8.60E-05	-	8.60E-04

Scenario [2]	1	4.58E-04	1.15E-02	-	1.20E-02
	2 (gloves)	4.58E -04	3.35E-03	-	3.81E-03
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	4.23E-05	-	4.23E -05
	2 (gloves)	-	4.23E -06	-	4.23E -06

Further information and considerations on scenario [2] - metaSPC 10: PT3 Concentrated teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2] – Consumer spraying and dusting model 2, Hand-held trigger spray	4.83E-02

metaSPC 11: PT3 RTU teat disinfectants – Iodine

Exposures following use of teat disinfectants from metaSPC 11 (up to 0.44% of total iodine)

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13 table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1]	1	-	8.80E-05	-	8.80E-05
Scenario [1.1]	2/Gloves	-	8.80E-06	-	8.80E-06
Scenario [1.2]	1	-	1.76E-03	-	1.76E-03
Scenario [1.2]	2/Gloves	-	1.76E-04	-	1.76E-04
Scenario [2.1]	1	4.38E-04	1.10E-02	-	1.15E-02
	2/Gloves	4.38E -04	3.20E-03	-	3.64E-03
Scenario [2.2]	Exposure is considered covered by the mixing and loading scenario.				
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	4.05E-05	-	4.05E -05
	2/Gloves	-	4.05E -06	-	4.05E -06

Further information and considerations on scenario [2.1] - metaSPC 11: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	4.62E-02

metaSPC 12: PT3 RTU teat disinfectants – Iodine

Exposures following use of teat disinfectants from metaSPC 12 (up to 0.60% of total iodine)

Due to new guidance the assessment has changed in accordance to HEAdhoc recommendation no. 13 table below is based on the assessment as included in the PAR.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1.1]	1	-	1.20E-04	-	1.20E-04
Scenario [1.1]	2/Gloves	-	1.20E-05	-	1.20E-05
Scenario [1.2]	1	-	2.40E-03	-	2.40E-03
Scenario [1.2]	2/Gloves	-	2.40E-04	-	2.40E-04
Scenario [2.1]	1	5.98E-04	1.50E-02	-	1.56E-02
	2/Gloves	5.98E-04	2.77E-03	-	3.37E-03
Scenario [2.2]	Exposure is considered covered by the mixing and loading scenario.				
Scenario [3]	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.				
Scenario [4]	1	-	5.52E-05	-	5.52E-05
	2/Gloves	-	5.52E-06	-	5.52E-06

Further information and considerations on scenario [2.1] - metaSPC 12: PT3 RTU teat disinfectants - Iodine: Local exposure concentration of iodine in air

Summary table: estimated exposure from professional uses	
Exposure scenario	**Iodine in air inhaled (mg/m³)**
Scenario [2.1] – Consumer spraying and dusting model 2, Hand-held trigger spray	6.30E-02

Combined scenarios

metaSPC 1: PT3 Concentrated teat disinfectants – Iodine

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1, 2, 3, 4]	Tier 1/ none	4.98E-04	1.30E-02	-	1.35E-02
	Tier 2/ Gloves	4.98E-04	3.69E-03	-	4.19E-03

metaSPC 2: PT3 RTU teat disinfectants – Iodine

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	5.78E-04	1.47E-02	-	1.52E-02
	Tier 2/ Gloves, coated coverall and boots	5.78E-04	2.70E03	-	3.27E-03
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	-	2.37E-03	-	2.37E-03
	Tier 2/ Gloves	-	2.37E-04	-	2.37E-04

metaSPC 3: PT3 RTU skin disinfectants - Iodine

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1, 2.1, 3]	Tier 1/ none	1.59E-04	4.40E-03	-	4.56E-03
	Tier 2/ Gloves	1.59E-04	1.20E-03	-	1.36E-03
Scenarios [1, 2.2, 3]	Tier 1/ none	3.54E-04	9.32E-03	-	9.68E-03
	Tier 2/ Gloves	3.54E-04	2.63E-03	-	2.99E-03

metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine

Summary table: combined systemic exposure from professional uses teat disinfection					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
metaSPC 4: PT3 RTU teat disinfectants – Iodine					
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	4.98E-04	1.26E-02	-	1.31E-02
	Tier 2/ Gloves	4.98E-04	3.65E-03	-	4.1E-03
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	-	2.05E-03	-	2.05E-03
	Tier 2/ Gloves	-	2.05E-04	-	2.05E-04
metaSPC 4: PT3 RTU skin disinfectants – Iodine					
Scenarios [1, 2.1, 3]	Tier 1/ none	5.47E-05	1.52E-03	-	1.57E-03
	Tier 2/ Gloves	5.47E-05	4.14E-04	-	4.68E-04
Scenarios [1, 2.2, 3]	Tier 1/ none	1.22E-04	3.22E-03	-	3.34E-03
	Tier 2/ Gloves	1.22E-04	9.07E-04	-	1.03E-03

metaSPC 5: RTU teat disinfectant – PVP-Iodine

Exposures following use of teat disinfectants from metaSPC 5 (up to 0.58% of total iodine) are covered by the ones following use of teat disinfectants from metaSPC 2 (up to 0.58% of total iodine). Therefore, there is no need for further investigation.

Comment eCA; calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2. The assessments results in the same RMM as for metaSPC2

metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario	Tier 1/ none	1.97E-04	5.48E-03	-	5.67E-03

s [1, 2.1, 3]	Tier 2/ Gloves	1.97E-04	1.49E-03	-	1.69E-03
Scenarios [1, 2.2, 3]	Tier 1/ none	4.40E-04	1.15E-02	-	1.20E-02
	Tier 2/ Gloves	4.40E-04	3.26E-03	-	3.70E-03

metaSPC 7: PT3 Surfaces disinfectants – Iodine

Spraying step is combined with pouring step or pumping step.

Summary table: combined systemic exposure from industrial uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 3] tier 1	1.93E-03	1.06E-01	No exposure	1.08E-01
Scenarios [1, 3] tier 2 – gloves and impermiable coverall	1.93E-03	3.04E-03	No exposure	4.96E-03
Scenarios [2, 3] tier 1	3.22E-03	1.19E-01	No exposure	1.22E-01
Scenarios [2, 3] tier 2 – gloves, impermeable coverall	3.22E-03	3.16E-03	No exposure	6.38E-03

metaSPC 8: PT3 Surfaces disinfectants – Iodine

Spraying step is combined with pouring step (scenario 1) or pumping step (scenario 2).

Summary table: combined systemic exposure from industrial uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 3] tier 1	1.02E-03	2.05E-01	No exposure	2.06E-01

Scenarios [1, 3] tier 2 – gloves and impermiable coverall	1.02E-03	3.84E-03	No exposure	4.87E-03
Scenarios [2, 3] tier 1	2.50E-03	2.67E-01	No exposure	2.69E-01
Scenarios [2, 3] tier 2 – gloves, impermeable coverall	2.50E-03	4.47E-03	No exposure	6.97E-03

metaSPC 9: PT4 CIP disinfectants for milking parlours – Iodine

Combination of pouring and pumping step is not relevant, and considered covered by the local risk assessment.

metaSPC 10: PT3 Concentrated teat disinfectants – Iodine

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1, 2, 3, 4]	Tier 1/ none	4.58E-04	1.24E-02	-	1.29E-02
	Tier 2/ Gloves	4.58E-04	3.44E-03	-	3.90E-03

metaSPC 11: PT3 RTU teat disinfectants – Iodine

Exposures following occasional uses of products from metaSPC 11 (up to 0.44% of total iodine)

Summary table: combined systemic exposure from professional uses					
Scenarios combined	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	4.38E-04	1.11E-02	-	1.16E-02
	Tier 2/ Gloves	4.38E-04	3.21E-03	-	3.65E-03
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	-	1.80E-03	-	1.80E-03
	Tier 2/ Gloves	-	1.80E-04	-	1.80E-04

metaSPC 12: PT3 RTU teat disinfectants – Iodine

Exposures following occasional uses of products from metaSPC 12 (up to 0.60% of total iodine)

Summary table: combined systemic exposure from professional uses

Scenarios combined	Tier/PPE	Estimated inhalation uptake (mg/kg bw/d)	Estimated dermal uptake (mg/kg bw/d)	Estimated oral uptake (mg/kg bw/d)	Estimated total uptake (mg/kg bw/d)
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	5.98E-04	1.52E-02	-	1.58E-02
	Tier 2/ Gloves	5.98E-04	2.79E-03	-	3.39E-03
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	-	2.46E-03	-	2.46E-03
	Tier 2/ Gloves	-	2.46E-04	-	2.46E-04

Non-professional exposure

Non-professional users are not expected to use products from the BPF. They can be exposed (secondary exposure) via residues in food. This is described in the paragraph "Risk for consumers via residues in food".

Exposure of the general public

Non-professional users are not expected to use products from the BPF. They can be exposed (secondary exposure) via residues in food. This is described in the paragraph "Risk for consumers via residues in food".

Dietary exposure

Risk for the general public (secondary exposure via oral route) is assessed to be safe as described in the IRG study "Discussion paper – iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety". This discussion paper is included of the ToxRA evaluations per metaSPC included in part 8 of IUCLID.
However, it should be noted that in this document for the Tier2 assessment it is assumed that the iodine content is reduced by 50% as the milk from various milking farms are mixed assuming that 50% of these farms do not use iodine based teat disinfection. Tier 2 includes a reduction in iodine concentration of 27% due to pasteurization, as was also taken in the EFSA (2013) opinion on the safety and efficacy of iodine compound (E2) as feed additives. Furthermore, 0.5 L consumption of milk was considered for both adults and children/toddlers, and is in line with the CAR for iodine.

Note eCA: dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. For the exposure to residues, the O'Brien study can be used. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered are included below:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account, based on 0.54% available iodine from metaSPC5. Other metaSPC are also calculated as this information was necessary for calculating the professional exposure due to use. All calculations are included in Annex 3.2; residues.
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable". However, as the residue exposure should be in line with the intende use, and as the amount of product is 5 ml per cow, independent whether the application is performed manually or auhtomatically, the worst case is automatic application and 3 times exposure. Therefore the exposure based on the O'Brien study, which was applied twice needs to be recalculated. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).
- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)

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

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (residues). It is noted that only the worst-case is shown in the table below, however, all calculations are included in the provided document as included in the annex.

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

Comparison of estimated daily iodine intakes compared to upper limit of post-milking teat-disinfection by manual dipping/spraying, based on the worst case of 0.54% available iodine. Intakes which exceed the UL are highlighted in red in the table below.

	Adults (0.45 L/day)	**Toddlers (0.46 L/day)**
	Estimated daily intake (µg/day) [% ofUL]	**Estimated daily intake (µg/day) [% ofUL]**
3x post-milking		
Intake from milk due to teat treatment	183 31	187 94
Total milk intake*	273 46	279 140
Total dietary intake**	458 76	375 188

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

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

Calculations are included in annex 3.2 (residues). It is noted that only the worst-case is shown above in the table, however, all calculations are included in the provided document as included in the annex.

Conclusion: Post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 31% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 46% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 76% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 94% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 140% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 188% of the UL.

List of scenarios

Some scenarios are theoretically envisageable but not relevant because not realistic or covered by the main scenario of residues in milk following teat disinfection. Indeed the exposure to residues in meat following use of teat disinfectants is covered by the exposure to residues in milk following the same use according to the CAR of iodine. The disinfection of animal housings takes place maximum 13 times per year according to the ESD for PT3 "veterinary hygiene biocidal products" so the exposure is very occasional (contrary to the 300 ays on 365 days of exposure for teat disinfection of cows). Furthermore, disinfection of animal housings takes generally place between batches, meaning that animals joining the slaughterhouses are not exposed to iodine of products used for animal housings disinfection. Disinfection of skin of farrowing animals. Disinfection of udders (new cows joining the herd) is not expected to be concomitant with teat disinfection. Disinfection in food industry and disinfection of milking installations and milking tanks are followed by a torough rinsing minimising the risk of residues.

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use[1]**	**Description of scenario**	**Subject of exposure[2]**
metaSPC 1,2,4,5,10,11,12: RTU teat disinfectants - iodine			
1.	Teat disinfection	Residues in milk after teat disinfection.	milk
Skin disinfection of farrowing animals (meta SPC 3 use 1, meta SPC 4 use 2, meta SPC 6 use 1)			
2.	Udder disinfection	Residues in milk after disinfection	Milk
Surface disinfection in animal housing (meta SPC 7 use 2, meta SPC 8 use 1)			
3.	Use in animal husbandry	Indirect exposure of animals by rubbing and licking of treated surfaces. No direct exposure is taken into account, as treatment takes place when no animals are present	Meat from animals from treated animal housing
Surface disinfection in professional kitchens and food industry (meta SPC 7 use 1, meta SPC 8 use 1)			
4.	Surface disinfection in food industry and professional kitchens	Residues in food exposure to treated surfaces.	Food exposure
CIP disinfection for milking equipment and CIP installation in food industry (meta SPC 9 use 1)			

5.	Surface disinfection from CIP installations and milking equipent	Residues in food and milk from teated surfaces.	Food/milk exposure.

Note eCA: scenario number 2-5 is added after commenting phase and discussion in WG.
Additional notes:

- Scenario 2 – Udders of cows and of pigs will be disinfected a few days before and one day after respectively calving and farrowing. Milk will be used for newborns and the mother and newborns will not go the the slaughter house. Therefore, no exposure to residues due to this use is envisaged. Additionally, the udder disinfection will be equal to the teat disinfection scenario (scenario 1), therefore covered by the assessment for teat disinfection.
- Scenario 3 – dietary exposure will be addressed for humans by indirect exposure by eating livestock from animal treated housing. The livestock exposure is included in section: risk assessment for animal health.
- Scenario 4 – dietary exposure will be addressed for humans by indirect exposure to food that has been in contact to treated surfaces.
- Scenario 5 – dietary exposure will be addressed for humans by indirect exposure to food from treated CIP installations or to food from treated milking equipment

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Scenario 1: Teat disinfection

A direct exposure of animals is determined for products of metaSPC 1, 2, 3, 4, 5, 6, 10, 11 (these are topical products applied on teats or skin).

According to the EMEA (European Agency for the Evaluation of Medicinal Products) summary report on iodine-containing products used for veterinary medicine, only small increases in serum iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue iodine concentrations. These results suggest limited livestock exposure and no-detailed risk assessment was therefore performed for animal health. This is supported by the EFSA 2013 opinion on the safety and efficacy of iodine compounds (E2) as feed additives, in which it was concluded that the iodine level in edible tissues/products is generally found to be highest in milk and not in meat. Calculations on residues in milk presented in the dietary assessment are therefore covering potential residues in meat and considered as sufficient for metaSPC 1, 2, 3, 4, 5, 6, 10 and 11.

Scenario 2: Skin disinfection

For this use the udders of cows and of pigs will be disinfected a few days before and one day after respectively calving and farrowing. Milk will be used for newborns and the mother and newborns will not go the the slaughter house. Therefore, no exposure to residues due to this use is envisaged.Moreover, the udder disinfection for cows is applied less frequent on a daily basis (1 time per day) compared to regular teat disinfections (2 times per day manually or 3 times per day automatically) and therefore is covered by the dietary risk assessment for teat disinfection (see dietary exposure section).

Scenario 3: Surface disinfection in animal housing

Livestock are not present when the animal housing is dinfected, therefore only indirect exposure of animals is determined for products included in metaSPC 7 and 8.
Worst case exposure assessment for the animals is performed and included in section: risk assessment animal health. In summery, for cows (worst case is calf) and pigs the indirect exposure via rubbing, eating of contaminated food, licking of sufaces is taken into account. For laying hens the consumption of contaminated food and contaminated flies is taken into account.
The calculation sheet is included in Annex 3.2; cidlines animal exposure.

Animal housing assessment

	Exposure via animal house spraying [mg/kg bw day]	$UL_{farm-animal}$ [mg/kg bw day]	% UL	**Acceptable (yes/no)**
Tier 1				
Scenario 2a calf	1.02	0.40	255	no
Scenario 2b: laying hen	0.214	0.68	31	yes

Scenario 2c: dairy cattle	0.121	0.38	32	yes
Scenario 2d: pigs	1.167	0.30	389	no
Tier 2*				
Scenario 2a calf	0.250	0.40	63	yes
Scenario 2b: laying hen	0.170	0.68	25	yes
Scenario 2c: dairy cattle	0.117	0.38	30	yes
Scenario 2d: pigs	0.373	0.30	124	yes, see argumen teation included in the conclusi on

*dermal absorption rate of 12% assumed as for human
Consumers exposure to iodine by consuming animal products e.g. meat produced from the livestock exposed to the biocidal product needs to be further considered. According to the DRAWG Draft proposal guidance WCCE (worst case consumer exposure) should be estimated. If the exposure is lower than 30% of the ADI, and in case where there is no particular concern in relation to the toxicity of the active substance, then an MRL evaluation is not required.

For consumer exposure, the standard food basket as defined in Commission Regulation (EU) 2018/782 is considered.
According to the standard food basket the theoretical maximum daily intake for animal origin product for an adult is:
2.0 kg for mammals (0.3 kg muscle, 0.05 kg fat, 0.1 kg liver, 0.05 kg kidney 1.5 kg milk), and 0.6 kg for poultry (0.3 kg muscle, 0.09 kg fat and skin in natural portions, 0.1 kg liver, 0.01 kg kidney, 0.1 kg egg).

The theoretical maximum consumption of the substance is therefore calculated as:
(0.373 mg/kg bw (based on fattening pig, worst case mammal, see table above) x 2.0 kg)
+ (0.170 mg/kg bw (poultry, see table above) x 0.6 kg)
= (0.746 + 0.102) mg/person
= 0.848 mg/person
Which is higher than the UL for adults (i.e. 600 µg/d for an Adult). However, the standard food basket does not reflect average food exposure as it takes into account 2.6 kg food intake from animal exposure per day, but is used as worst case approach in order to find out if an MRL is necessary for Biocidal use. Moreover, it should be noted that calculations made represent worst case conditions. For example for dietary intake of mammalian origin, the amount of iodine determined for a fattening pig was used (i.e. 0.373 mg/kg bw/day). However, the majority of dietary daily consumption from mammalian origin comes from milk (i.e. 1.5 L) and obvisously humans do not drink milk from pigs.
Performing a refined calculation taking into account the consumption of pig meat and milk from dairy cows, the following human consumption is calculated:
(0.373 mg/kg bw (based on fattening pig, worst case mammal, see table above) x 0.5 kg)
+ (0.117 mg/kg (based on dairy cow) x 1.5 kg) + (0.170 mg/kg bw (poultry, see table above) x 0.6 kg)
= (0.187 + 0.176 + 0.102) mg/person
= 0.465 mg/person
Which is below the UL for adults (i.e. 600 µg/d for an Adult).

However, as the guidance Guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides (adopted by CVMP at January 2015, into force first of August 2015) was not into force for biocidal product assessments which considers a two-year time frame, we consider a more realistic food consumption approach.

Based on Primo 3.1 which contains the most recent compution data, for chonic consumption the following information is included.
For chronic consumption of swine, bovine, poultry the max. intake is reflected by respectively 4.4 g/kg bw/d (SE general), 4.4 g/kg bw/d (SE general), 1.4595 GEMS/Food G10 g/kg bw/d.
For a 60 kg adult this results in a daily exposure of : 246 g swine/bovine and 88 g poultry.
For a 10 kg toddler toddler this results in a daily exposure of: 44 g swine/bovine and 15 g poultry.
Again, these are worst case chronic data which are taken into account for average daily exposure, with high differenes between countries.
For the chronic daily food exposure assessment, the amount of mammals and poultry are summed up:

Adults:
(246/1000) kg x 0.373 mg/kg bw (based on fattening pig, worst case mammal, see table above) + (88/1000) kg x 0.170 mg/kg bw (poultry, see table above) = (0.092 + 0.015) mg/adult = 0.107 mg/adult = 107 µg/d.

Toddler:
(44/1000) kg x 0.373 mg/kg bw (based on fattening pig, worst case mammal, see table above) + (15/1000) kg x 0.170 mg/kg bw (poultry, see table above) = (0.016 + 0.003) mg/toddler = 0.019 mg/toddler = 19 µg/d.

As the calculated residues exposure of 107 µg/d and 19 µg/d for respectively adults and toddlers are well below their UL when based on worst case assumptions (i.e. 600 µg/d and 200 µg/d), no adverse health effects are expected after indirect exposure to residues by eating meat from animal origin from animal treated use included in metaSPC 7 and 8.

In addition to meat, people can also eat other products from animal origin such as milk products and eggs. According to Primo 3.1 the maximum milk intake from cattle is 59.73 mg/ kg /bw/day for toddlers (based on intake data for NL toddlers) and for adults this is 12.3868 mg/kg bw (DE general).
For a 60 kg adult this results in a daily exposure of: 743.208 g/day.
For a 10 kg toddler toddler this results in a daily exposure of: 123.868 g/day.

Chronic exposure to eggs is 1.3448 mg/kg bw (UK infant) for children and 0.883 mg/kg bw for adults (SE general).

For a 60 kg adult this results in a daily exposure of: 52.98 g/day.
For a 10 kg toddler toddler this results in a daily exposure of: 13.448 g/day.

Adults:
(743/1000) kg x 0.117 mg/kg bw (based on dairy cow, see table above) + (52.98/1000 * 0.170 mg/kg bw (poultry, see table above) = 0.096 mg/adult = 96 µg/d.

Toddler:

(124/1000) kg x 0.117 mg/kg bw (based on dairy cow, see table above) + (13/1000) kg x 0.170 mg/kg bw (poultry, see table above) = 0.017 mg/toddler = 17 µg/d.

This thus results in an exposure of 107 µg/d for meat products and 96 µg/d for milk and eggs for an adult, resulting in a total daily exposure of 203 µg/d, which is well below the respective UL of 600 µg/d. For toddlers this results in a daily total intake of 36 µg/d (i.e. 19 µg/d for meat and 17 µg/d for milk and eggs) which is also well below the respective UL of 200 µg/d. In conclusion, no adverse health effects are expected after indirect exposure to residues by eating products from animal origin from animal treated use included in metaSPC 7 and 8.

Scenario 4: Surface disinfection in professional kitchens and food industry

For products used in PT4 (food industry and disinfection of milking parlours systems) exposure of humans (primary or secondary) of products included in metaSPC7 and 8 is not expected, as disinfection are followed by a torough rinsing with water minimising the risk of residues.

A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.
Tested formulation for metaSPC8 is equal to the max. concentrations of the co-formulants which are max. in iodine equivalents and in phosphoric acid included this metaSPC.
A 10% diluted product is used for the test containing 3% of the active substance, which is worst case to the in-use dilution of products included in metaSPC7 and 8 which are used in the food industry (max 0.025% total iodine for metaSPC7 and 0.024% if total iodine for metaSPC9).

The following was concluded from the study:
The iodine concentration found in rinsing water after application of 10% solution of a formulation for metaSPC8 containing max iodine equivalents and phosphoric acid included in this metaSPC by spraying is 0.0489 g/m^2.
The iodine concentration found on the ionox surface after application of 10% solution of a formulation for metaSPC8 containing max iodine equivalents and phosphoric acid included in this metaSPC by spraying is below the quantification limit of analytical method (3ppm).

As the residues found on the inox surface is below the quantificiation limit of analytical method (3ppm equal to 0.0003%), no adverse health effects are expected after indirect exposure to residues by surfaces treated with products included in metaSPC7 and 8.

Scenario 5: Surface disinfection from CIP installations and milking equipment

For products included in metaSPC9 to be used in CIP installations and milking equipment (food industry and disinfection of milking parlours systems) exposure of humans is not expected, as disinfection are followed by a torough rinsing minimising the risk of residues.
A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.

A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.
Tested formulation for metaSPC8 is equal to the max. concentrations of the co-formulants which are max. in iodine equivalents and in phosphoric acid included this metaSPC.

A 10% diluted product is used for the test, which is worst case to the in-use dilution of products included in metaSPC9 which are used CIP installations in the food industry or in milking equipment (max 0.001% total iodine).

As the residues found on the inox surface is below the quantificiation limit of analytical method (3ppm equal to 0.0003%), no adverse health effects are expected after indirect exposure to residues by CIP installations and milking equipment treated with products included in metaSPC9.

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

Estimating transfer of iodine into food as a results of non-professional use is not expected.

Aggregated exposure

Summary of exposure assessment

Cumulative exposures is relevant for metaSPC 2 and 9 (primary and secondary exposures) for professionals in dairy farmhouses.

Note eCA:
As the exposure to products included in metaSPC9 covered by local effects only, no combined systemic exposure is envisaged, as only systemic exposure could occur during use of products included in metaSPC2.
Therefore the combined exposure of metaSPC2 and 9 are covered by the separate risk assessment for metaSPC2 and 9.

However, for the professional use for teat disinfection on cows and skin disinfection on cows, the use PPE for either use is necessary to conclude safe use. Furthermore, for the professional use for teat disinfection and the disinfection of animal housing, the use PPE or PPE/RPE for either use is necessary to conclude safe use.
Based on the %UL for combined exposure, taking into account iodine from dietary exposure per use, products in this BPF for the exposure scenarios cannot be used at the same time or otherwise would exceed the UL, which is considered not acceptable.
Therefore, the following risk mitigation measure needs to be included.

In case a combination of post-milking disinfection, disinfection of animal housing or disinfection of milking clusters is necessary, an iodine based product can only be used for one of these uses.
In case a combination of post-milking disinfection of cows and skin disinfection of cows is necessary, this cannot be performed by the same persone, or an iodine based product can only be used for one of these uses.

C. RISK CHARACTERISATION FOR HUMAN HEALTH

Reference values to be used in Risk Characterisation for iodine

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AEL = Upper Intake Level (UIL)	Assessment report on Iodine (13 December 2013 – Sweden)	n.a.	n.a.	n.a.	UIL: 600 µg/d for adults ⇔ 0.01 mg/kg bw /day and 200 µg/d for children
AEC = OEL (occupational exposure limit)	Assessment report on Iodine (13 December 2013 – Sweden)	n.a.	n.a.	n.a.	0.1 ppm/ 1 mg/m3 (8h workday)

Reference values to be used in Risk Characterisation for phosphoric acid

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
OEL	n.a.	n.a.	n.a.	n.a.	1 mg/m3 (8h workday)

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
Iodine is included in the table 1 (allowed substances) with no restriction.	Commission Regulation (EU) N°37/2010 on MRL		No restriction
Trigger value for residues in livestock	Technical Notes for Guidance: Guidance on Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products		0.004 mg/kg/day

Indeed active substance iodine may be expected to lead to residues in food or feed following uses proposed in metaSPC 1, 2, 3, 4, 5, 6, 7 (PT3 and 4), 8 (PT3 and 4), 9.

The guidance "Technical Notes for Guidance on Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products" [1] has been followed. First trigger value for residues in livestock is then 0.004 mg/kg/day. ADI value is not available for iodine [2]. Other reference doses are used according to data from literature (included in IRG [3]):

1. NOAEL value of 2.5 mg iodine /kg bw/d [3]

NOAEL of 2.5 mg iodine/kg bw/d is derived after administration of EDDI (3,5-diiodosalicylic acid, ethylenediaminedihydriodide) to pregnant cows. **Reference dose$_{\text{dairy cows}}$ = 2.5 mg iodine/kg bw/d**

Reference dose$_{\text{other animals}}$ = 0.25 mg iodine/kg bw/d

2. NOAEL of 0.42 mg/kg bw/d [3]

NOAEL of 0.42 mg/kg bw/d was derived for rats after oral exposure *via* drinking water for 100 days. Using the NOAEL derived for iodine from a rat study as reference dose for dairy cows is considered to represent a conservative worst-case based on differences in thyroid physiology and homeostasis of thyroid hormones in non-rodent mammalian species vs. rodents. In non-rodent mammals, > 99% of the thyroid hormones (T4 and T3) are bound to the thyroxin-binding globulin (TBG). This thyroid hormone storage function of TBG leads to low concentrations of the "free" hormone form circulating in the blood being available for hormone metabolism. In the rat, there is no such binding protein for thyroid hormones leading to higher amounts of the "free" hormone form, and thus to a higher metabolic hormone turn-over. Based on these considerations, rats are considered to be more susceptible to iodine than non-rodent mammalian species and, as a consequence, an assessment factor (AF) for the deduction of a reference dose for dairy cows is not considered to be required. This rationale is further supported by a comparison of the NOAEL from the rat study (0.42 mg
iodine/kg bw/d) with the NOAEL derived in pregnant cows (2.5 mg iodine/kg bw/d).

Reference dose$_{\text{dairy cows and other animals}}$ = 0.42 mg iodine/kg bw/d

3. Internal exposure of 0.40 mg iodine/kg bw/d [3]

A third option is to consider the EFSA data: The EFSA Panel on additives and products or substances used in animal feed (FEEDAP) has published two Scientific Opinions related to iodine compounds as additives in feedingstuff of various animal species (EFSA, 2005; EFSA, 2013). It has to be noted that the main objective/focus of these Scientific Opinions was on consumer safety. However, it can be concluded that iodine supplementation of complete feed in the range of 5-10 mg/kg feed dry matter (DM) is without adverse effects in lactating cows when a weight of evidence (WoE) approach is applied. Since the Panel considered 50 mg/kg complete feed as a safe standard upper value for dairy cows (EFSA, 2005) and since adverse effects at supplemented iodine levels of 5-10 mg/kg feed DM were only occasionally reported (EFSA, 2013), it is considered reasonable to use the 10 mg/kg feed DM as the starting point for the calculation of an orientating reference dose for dairy cows: Taking into account
10 mg/kg feed DM in complete feed, a daily feed intake of 26 kg feed DM/dairy cow/day as well as a body weight of 650 kg/dairy cow according to the DRAWG proposal on livestock exposure [1], internal exposure is calculated to be 0.40 mg iodine/kg bw/d which can be considered a conservative safe iodine level in dairy cows (i.e. orientating reference dose).

Reference dose$_{\text{dairy cows only}}$ = 0.40 mg iodine/kg bw/d

Exposures are found to be below the reference doses mentioned above. This is also fully coherent with evaluation of the European Medicinal Agency (EMA) which already assessed iodine as iodine is also a veterinary medicinal substance. Conclusions of EMA in the Committee for Veterinary Medicinal Products on Iodine CVMP report [4] is that "it would be inappropriate to elaborate MRLs for iodine". Indeed Iodine is listed in the table 1 of the annex to Commission Regulation (EU) No 37/2010 with "No MRL required", for "All food producing species". EMA bases its assessment on uses of iodine based products as teat disinfectant, as topical preparations for prevention of infections in wounds and as preparations for oral and parenteral administration. The uses investigated by EMA cover the uses preconized in the BPF Iodine based products – CID LINES NV so the assessment

conclusion "MRL not required" for iodine is compatible with products of the BPF Iodine based products – CID LINES NV. Therefore we believe there is no need to set new or to amend existing maximum residue levels (MRLs) for iodine 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. Risk Mitigation Measures are therefore not needed concerning residues in food.

[1] Technical Notes for Guidance on Estimating Livestock Exposure to Biocidal Active Substances used in Biocidal Products.

[2] Assessment report: Evaluation report on Iodine (including PVP-iodine) Product types 1, 3, 4, 22. Sweden, 13 December 2013.

[3] Iodine Registration (IRG) Group: Considerations on animal health: exposure and risk assessment for dairy cows treated with iodine-based teat-disinfectants, 11t June 2015.

[4] European Medicines Agency – CVMP report on Iodine

Risk for industrial users:

Systemic effects

- Only the worst case is included in the table below.
- Intakes which exceed the UL are highlighted in red in the table below.

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[2]
metaSPC 7: PT4: Surfaces disinfectants - Iodine					
Scenario [1] pouring	1/ none	3.56E-02	356	371	401
	2/ Gloves	4.13E-04	4	19	50
Scenario [2] pumping	1/ none	4.98E-02	498	513	543
	2/ Gloves	1.84E-03	18	33	64
Scenario [3] Spraying	1/ none	1.75E-02	175	190	221
	2/ gloves, coated coverall	2.28E-03	23	38	69
metaSPC 8: PT4: Surfaces disinfectants - Iodine					
Scenario [1] pouring	1/ none	3.55E-02	355	370	401
	2/ Gloves	4.12E-04	4	19	50
Scenario [2] pumping	1/ none	4.98E-02	498	513	543
	2/ Gloves	1.84E-03	18	33	64
Scenario [3] Spraying	1/ none	1.68E-02	168	183	214
	2/ gloves& coated coverall	2.19E-03	22	37	68

[1] Total milk intake is the sum of the estimated additional intake resulting from the background milk value of 200 µg/L (EFSA 2013), considering 0.45 L intake for an adult.
[2] Total dietary intake is the sum of the estimated additional intake resulting from the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult based on UK data (2008) considering 0.45 L intake for an adult.

Combined scenarios

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[2]
metaSPC 7: PT4: Surfaces disinfectants - Iodine					
Scenarios [1, 3]	1/ none	5.30E-02	530	545	576
	2/ Gloves and coated coverall	2.68E-03	27	42	73
Scenarios [2, 3]	1/ none	6.72E-02	672	687	718
	2/ gloves, coated coverall	4.10E-03	41	56	87
metaSPC 8: PT4: Surfaces disinfectants - Iodine					
Scenarios [1, 3]	1/ none	5.23E-02	523	538	569
	2/ Gloves and coated coverall	2.60E-03	26	41	72
Scenarios [2, 3]	1/ none	6.65E-02	665	680	711
	2/ gloves, coated coverall	4.02E-03	40	55	86
metaSPC 9: PT4: CIP disinfectants used in food industry- Iodine					
Combination of exposures via pouring and pumping is and considered covered by the local risk assessment.					

[1] Total milk intake is the sum of the estimated additional intake resulting from the background milk value of 200 µg/L (EFSA 2013), considering 0.45 L intake for an adult.
[2] Total dietary intake is the sum of the estimated additional intake resulting from the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult based on UK data (2008) considering 0.45 L intake for an adult.

Local effects

Inhalation
As an OEL exists for iodine, estimation of occupational exposure is performed.

Scenario	Tier	OEL mg/m³	Iodine in air inhaled mg/m³	Iodine in air inhaled/ OEL (%)	Acceptable (yes/no)
MetaSPC 7: PT4: Surfaces disinfectants - Iodine					
S1	1	1	0.0330	3.30	Yes
S2	1	1	0.7722	77.22	Yes
S3	1	1	0.026	2.6	Yes
MetaSPC 8: PT4: Surfaces disinfectants – Iodine					
S1	1	1	0.038	3.8	Yes
S2	1	1	0.884	88.4	Yes
S3	1	1	0.025	2.5	Yes

As an OEL exists for phosphoric acid, estimation of occupational exposure is performed.

Scenario	Tier	OEL mg/m³	Iodine in air inhaled mg/m³	Iodine in air inhaled/ OEL (%)	Acceptable (yes/no)
MetaSPC 9: PT4: Surfaces disinfectants – phsophoric acid					
S1	1	1	8.1E-04	0.08	Yes
S2	1	1	8.1E-04	0.08	Yes

Dermal route
A qualitative assessment is performed for products from metaSPC 7-9 (metaSPC7 classified as H318 and metaSPC8 classified as H315 and H318, and metaSPC9 classified as H314).

Hazard		**Exposure**					**Risk**
MetaSPC 8: PT4: Surfaces disinfectants - Iodine							
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Relevant RMMM & PPE**	**Conclusion on risk**
MetaSPC 7: PT4: Surfaces disinfectants - Iodine							
High	Eye Dam. H318	Industrial	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work	Acceptable RMM are achievable and PPE are

						area PPE: - Chemical googles or Face shield - Gloves	realistic
High	Eye Dam. H318	Industrial	S1 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles or Face shield - Gloves	Acceptable RMM are achievable and PPE are realistic
MetaSPC 8: PT4: Surfaces disinfectants – Iodine							
High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	Indus-trial	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	industrial	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves	Acceptable RMM are achievable and PPE are realistic

						- Face shield - Protection coverall	
metaSPC 9: PT4: CIP disinfectants used in food industry – Iodine							
Very high	Skin. Corr. 1A H314	Indus-trial	S1 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
Very high	Skin. Corr. 1A H314	industrial	S2 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic

Conclusion

Risk from the industrial use of products included in metaSPC7-9 are acceptable when wearing the following RMM:

metaSPC7 PT4:

- During pouring of the concentrated product: Wear chemical resistant gloves and eye/face protection.
- During pumping of the product: Wear chemical resistant gloves and eye/face protection.
- During spraying of the product: Wearchemical resistant gloves, coated coverall

metaSPC8 PT4:

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and coated coverall, and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves, coated coverall

metaSPC9 PT4:

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.

Risk for professional users

Systemic effects

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

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
metaSPC 1: PT3 concentrated teat disinfectants – Iodine						
Scenario [1] Mixing/loading	1/ none	5.00E -04	5	16	31	62
	2/ Gloves	5.00E -05	1	12	27	58
Scenario [2] Application by trigger spraying	1/ none	1.30E-02	130	141	156	187
	2/ Gloves	4.14E-03	41	53	68	99
Scenario [3] Cleaning of teats	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
Scenario [4] Cleaning of equipment	1/ none	4.60E-05	0	12	27	58
	2/ Gloves	4.60E -06	0	11	26	57
metaSPC 2: PT3 RTU teat disinfectants – Iodine						
Scenario [1.1] Mixing/loading	1/ none	1.16E-04	1	12	27	58
	2/ Gloves	1.16E-05	0	11	26	57
Scenario [1.2] Mixing/loading	1/ none	2.32E-03	23	40	55	86
	2/ Gloves	2.32E-04	2	19	34	65
Scenario [2.1] Application by trigger spraying	1/ none	1.51E--02	151	162	177	208
	2/ Gloves, coated coverall and boots	3.26E-03	33	44	59	90

Scenario [2.2] Application by manual dipping	Exposure is considered covered by the mixing and loading scenario.					
Scenario [3] Cleaning of teats	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
Scenario [4] Cleaning of equipment	1/ none	5.34E-05	1	18	33	64
	2/ Gloves	5.34E-06	0	17	32	63
metaSPC 3: PT3 RTU skin disinfectants – Iodine						
Scenario [1] Mixing/loading	1/ none	2.90E-04	3	not applicable	18	49
	2/ Gloves	2.90E-05	0	not applicable	15	46
Scenario [2.1] Spraying application, skin disinfection cow	1/ none	4.14E-03	41	not applicable	56	87
	2/ Gloves	1.32E-03	13	not applicable	28	59
Scenario [2.2] Spraying application, skin disinfection sow	1/ none	9.25E-03	93	not applicable	108	138
	2/ Gloves	2.94E-03	29	not applicable	44	75
Scenario [3] Cleaning of equipment	1/ none	1.33E-04	1	not applicable	16	47
	2/ Gloves	1.33E-05	0	not applicable	15	46
metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine						
Teat disinfectant						
Scenario [1.1] Mixing/loading	1/ none	1.00E-04	1	12	27	58
	2/ Gloves	1.00E-05	0	11	26	57
Scenario [1.2] Mixing/loading	1/ none	2.00E-03	20	37	52	83
	2/ Gloves	2.00E-04	2	19	34	65
Scenario [2.1] Application by trigger spraying	1/ none	1.30E-02	130	141	156	187
	2/ Gloves	4.14E-03	41	53	67	98
Scenario [2.2] Application by manual dipping	Exposure is considered covered by the mixing and loading scenario.					
Scenario [3] Cleaning of teats	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
Scenario [4]	1/	4.60E-05	0	17	32	63

Cleaning of equipment	none					
	2/ Gloves	4.60E-06	0	17	32	63
Skin disinfectant						
Scenario [1] Mixing/loading	1/ none	1.00E-04	1	not applicable	16	47
	2/ Gloves	1.00E-05	0	not applicable	15	46
Scenario [2.1] Spraying application, skin disinfection cow	1/ none	1.43E-03	14	not applicable	29	60
	2/ Gloves	4.54E-04	5	not applicable	20	50
Scenario [2.2] Spraying application, skin disinfection sow	1/ none	3.19E-03	32	not applicable	47	78
	2/ Gloves	1.01E-03	10	not applicable	25	56
Scenario [3] Cleaning of equipment	1/ none	4.60E-05	0	not applicable	15	46
	2/ Gloves	4.60E-06	0	not applicable	15	46
metaSPC 5: RTU teat disinfectant – PVP-Iodine						
calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2 in the embedded document for professional exposure. The assessments results in the same RMM as for metaSPC2.						
metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine						
Scenario [1] Mixing/loading	1/ none	3.60E-04	4	not applicable	19	49
	2/ Gloves	3.60E-05	0	not applicable	15	46
Scenario [2.1] Spraying application, skin disinfection cow	1/ none	5.15E-03	51	not applicable	66	97
	2/ Gloves	1.64E-03	16	not applicable	31	62
Scenario [2.2] Spraying application, skin disinfection sow	1/ none	1.15E-02	115	not applicable	130	161
	2/ Gloves	3.65E-03	37	not applicable	52	82
Scenario [3] Cleaning of equipment	1/ none	1.66E-04	2	not applicable	17	47
	2/ Gloves	1.66E-05	0	not applicable	15	46
metaSPC 7: PT3 Concentrated surfaces disinfectants – Iodine						
Scenario [1] pouring	1/ none	3.56E-02	356	not applicable	371	401
	2/ Gloves	4.13E-04	4	not applicable	19	50
Scenario [2]	1/ none	4.98E-02	498	not applicable	513	543

pumping	2/ Gloves	1.83E-03	18	not applicable	33	64
Scenario [3] spraying	1/ none	7.20E-02	720	not applicable	735	766
	2/ Gloves, coated coverall	6.12E-03	61	not applicable	76	107
	2/ Gloves, impermeable coverall	4.55E-03	46	not applicable	61	91
metaSPC 8: PT3 Concentrated surfaces disinfectants – Iodine						
Scenario [1] pouring	1/ none	1.69E-01	1690	not applicable	1705	1736
	2/ Gloves	1.76E-03	18	not applicable	33	63
Scenario [2] pumping	1/ none	2.33E-01	2326	not applicable	2341	2371
	2/ Gloves	3.86E-03	39	not applicable	54	84
Scenario [3] spraying	1/ none	6.83E-02	683	not applicable	698	729
	2/ Gloves, coated coverall	5.80E-03	58	not applicable	73	104
	2/ Gloves, impermeable coverall	4.31E-03	43	not applicable	58	89
metaSPC 9: PT4: CIP disinfectants used in food industry- Iodine						
Combination of exposures via pouring and pumping is and considered covered by the local risk assessment.						
metaSPC 10: PT3 Concentrated teat disinfectants – Iodine						
Scenario [1] Mixing/loading	1/ none	8.60E-04	9	20	35	66
	2/ Gloves	8.60E-04	1	12	27	58
Scenario [2] Application by trigger spraying	1/ none	1.20E-02	120	131	146	177
	2/ Gloves	3.81E-03	38	49	64	95
Scenario [3] Cleaning of teats	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
Scenario [4] Cleaning of equipment	1/ none	4.23E -05	0	12	27	58
	2/ Gloves	4.23E -06	0	11	26	57
metaSPC 11: PT3 RTU teat disinfectants – Iodine						

Scenario [1.1] Mixing/loading	1/ none	8.80E-05	1	10	25	56
	2/ Gloves	8.80E-06	0	10	25	55
Scenario [1.2] Mixing/loading	1/ none	1.76E-03	18	32	47	78
	2/ Gloves	1.76E-04	2	16	31	62
Scenario [2.1] Application by trigger spraying	1/ none	1.14E-02	114	124	139	170
	2/ Gloves	3.64E-03	36	46	61	92
Scenario [2.2] Application by manual dipping	Exposure is considered covered by the mixing and loading scenario.					
Scenario [3] Cleaning of teats	Exposure of professionals considered to be negligible during cleaning of teats by wiping with cloth: removal of dried residues from post-milking treatment.					
Scenario [4] Cleaning of equipment	1/ none	4.05E -05	0	15	30	60
	2/ Gloves	4.05E -06	0	14	29	60

[1] Values derived from post-application use are included for scenarios that include post-application teat-disinfection uses, and is non-applicable for use on surfaces or for skin disinfection.
[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013), considering 0.45 L intake for an adult.
[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) only applicable for scenario 1 and 2, the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for toddler based on UK data (2008) considering 0.45 L intake for an adult.

Calculation sheet is included in annex 3.2. It is noted that besides the worst case, all worst cases per metaSPC are included.

Local effects

Inhalation
As an OEL exists for iodine, estimation of occupational exposure is performed.

Scenario	**Tier**	**OEL mg/m³**	**Iodine in air inhaled mg/m³**	**Iodine in air inhaled/ OEL (%)**	**Acceptable (yes/no)**
metaSPC 1: PT3 concentrated teat disinfectants – Iodine					
S2	1	1	0.0525	5.25	Yes
metaSPC 2: PT3 RTU teat disinfectants – Iodine					
S2.1	1	1	0.0609	6.09	Yes
metaSPC 3: PT3 RTU skin disinfectants - Iodine					
S2.1 and S2.2	1	1	0.152	15.2	Yes
metaSPC 4: PT3 RTU teat disinfectants and skin disinfectant					
S2.1, teat	1	1	0.0525	5.25	Yes

disinfectant					
S2.1 and S2.2, skin disinfectant	1	1	5.25E-02	5.25	Yes
metaSPC 5: RTU teat disinfectant – PVP-Iodine					
calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2 in the embedded document for professional exposure. The assessments results in the same RMM as for metaSPC2.					
metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine					
S2.1 and S2.2	1	1	0.189	18.9	Yes
metaSPC 7: PT3 Concentrated surfaces disinfectants – Iodine					
S1 pouring	1	1	0.033	3.3	Yes
S2 pumping	1	1	0.772	77.2	Yes
S3 spraying	1	1	0.048	4.8	Yes
metaSPC 8: PT3 Surfaces disinfectants – Iodine					
S1 pouring	1	1	0.038	3.8	Yes
S2 pumping	1	1	0.884	88.4	Yes
S3 spraying	1	1	0.0426	4.26	Yes
metaSPC 10: PT3 Concentrated teat disinfectants – Iodine					
S2	1	1	0.0483	4.83	Yes
metaSPC 11: PT3 RTU teat disinfectants – Iodine					
S2.1	1	1	0.0462	4.62	Yes
metaSPC 12: PT3 RTU teat disinfectants – Iodine					
S2.1	1	1	0.063	6.30	Yes

As an OEL exists for phosphoric acid, estimation of occupational exposure is performed.

Scenario	**Tier**	**OEL mg/m³**	**Iodine in air inhaled mg/m³**	**Iodine in air inhaled/ OEL (%)**	**Acceptable (yes/no)**
MetaSPC 9: PT4: Surfaces disinfectants – phsophoric acid					
S1	1	1	8.1E-04	0.08	Yes
S2	1	1	8.1E-04	0.08	Yes

Dermal route

A qualitative assessment is performed for products from metaSPC 1, 3, 7-10, 12 (metaSPC1, 7 and 10 classified as H318 and metaSPC8 classified as H315 and H318, and metaSPC9classified as H314).

For metaSPC1 and 10 only the concentrated product is classified, therefore the qualitative assessment is only performed for the mixing and loading phase.

Summary table: estimated local exposure from professional uses							
Hazard category	**Effects in terms of C&L**	**Who is exposed**	**Taskes, uses, processes**	**Potential exposure route**	**Frequency and duration**	**Relevant RMMM & PPE**	**Conclusion on risk**

					of potential exposure		
MetaSPC 1: PT3 concentrated teat disinfectants – Iodine (only during mixing and loading of spraying device) **MetaSPC 7: PT3: Surfaces disinfectants – Iodine** **metaSPC 10: PT3 Concentrated teat disinfectants – Iodine(only during mixing and loading of spraying device)**							
High	Eye Dam. H318	Professional	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles or Face shield - Gloves	Acceptable RMM are achievable and PPE are realistic
High	Eye Dam. H318	Professional	S1 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles or Face shield - Gloves	Acceptable RMM are achievable and PPE are realistic
High	Eye Dam. H318	Professional	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles or Face shield - Gloves	Acceptable RMM are achievable and PPE are realistic
MetaSPC 8: PT3: Surfaces disinfectants – Iodine							

High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	Professional	S1 loading product into spraying device (pouring)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
High	Skin. irrit. Cat 2, H315, Eye dam. Cat. 1, H318	Professional	S2 loading product into spraying device (pumping)	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
metaSPC 9: PT3: CIP disinfectants for milking parlours – Iodine							
Very high	Skin. Corr. 1A H314	Professional	S1 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
Very high	Skin. Corr. 1A H314	Professional	S2 loading product into	Skin	Few minutes or	RMM - trained	Acceptable

			the contained connected to CIP system	Eye (splashes, hand to eye transfer)	less per day	professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	RMM are achievable and PPE are realistic
metaSPC 9: PT3: CIP disinfectants for milking parlours – Iodine							
Very high	Skin. Corr. 1A H314	Professional	S1 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic
Very high	Skin. Corr. 1A H314	Professional	S2 loading product into the contained connected to CIP system	Skin Eye (splashes, hand to eye transfer)	Few minutes or less per day	RMM - trained professionals - regular cleaning of equipments and work area PPE: - Chemical googles - Gloves - Face shield - Protection coverall	Acceptable RMM are achievable and PPE are realistic

Combined scenarios

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

Task/ Scenario	Tier/ PPE	Estimated uptake (mg/kg bw/d)	% UL (0.01 mg/kg bw/day) due to biocidal use	% UL (0.01 mg/kg bw/day) due to biocidal use + iodine from milk due to teat treatment[1]	% UL (0.01 mg/kg bw/day) due to biocidal use + total milk intake[2]	% UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake[3]
metaSPC 1: PT3 concentrated teat disinfectants – Iodine						
Scenarios [1, 2, 3, 4]	1/ none	1.35E-02	135	147	162	193
	2/ Gloves	4.19E-03	42	53	68	99
metaSPC 2: PT3 RTU teat disinfectants – Iodine						
Scenarios [1.1, 2.1, 3, 4]	1/ none	1.52E-02	152	163	178	209
	2/ Gloves	3.27E-03	33	44	59	90
Scenarios [1.2, 2.2, 3, 4]	1/ none	2.37E-03	24	41	56	87
	2/ Gloves	2.37E-04	2	19	34	65
metaSPC 3: PT3 RTU skin disinfectants – Iodine						
Scenarios [1, 2.1, 3]	1/ none	4.56E-03	46	not applicable	61	91
	2/ Gloves	1.36E-03	14	not applicable	29	59
Scenarios [1, 2.2, 3]	1/ none	9.68E-03	97	not applicable	112	143
	2/ Gloves	2.99E-03	30	not applicable	45	76
metaSPC 4: PT3 RTU teat and skin disinfectants – Iodine						
Teat disinfectant						
Scenarios [1.1, 2.1, 3, 4]	1/ none	1.31E-02	131	142	157	188
	2/ Gloves	4.15E-03	42	53	68	99
Scenarios [1.2, 2.2, 3, 4]	1/ none	2.05E-03	20	37	52	83
	2/ Gloves	2.05E-04	2	19	34	65
Skin disinfectant						
Scenarios [1, 2.1, 3]	1/ none	1.57E-03	16	not applicable	31	62
	2/ Gloves	4.68E-04	5	not applicable	20	51
Scenarios [1,	1/	3.34E-03	33	not	48	79

2.2, 3]	none			applicable		
	2/ Gloves	1.03E-03	10	not applicable	25	56
metaSPC 5: RTU teat disinfectant – PVP-Iodine						
calculations for metaSPC5 are included in the calculation sheets included in Annex 3.2 in the embedded document for professional exposure. The assessments results in the same RMM as for metaSPC2.						
metaSPC 6: PT3 RTU skin disinfectant – PVP-iodine						
Scenarios [1, 2.1, 3]	1/ none	5.67E-03	57	not applicable	72	103
	2/ Gloves	1.69E-03	17	not applicable	32	63
Scenarios [1, 2.2, 3]	1/ none	1.20E-02	120	not applicable	135	165
	2/ Gloves, coated coverall and boots	3.70E-03	37	not applicable	52	83
metaSPC 7: PT3 Concentrated surfaces disinfectants – Iodine						
Scenario [1,3] pouring	1/ none	1.08E-01	1075	not applicable	1090	1121
	2/ Gloves, coated coverall	4.96E-03	50	not applicable	65	95
Scenario [2,3] pumping	1/ none	1.22E-01	1217	not applicable	1232	1263
	2/ Gloves, impermeable coverall	6.38E-03	64	not applicable	79	110
metaSPC 8: PT3: Surfaces disinfectants - Iodine						
Scenario [1,3] pouring	1/ none	2.06E-01	2056	not applicable	2071	2102
	2/ Gloves, coated coverall	4.87E-03	49	not applicable	64	94
Scenario [2,3] pumping	1/ none	2.69E-01	2691	not applicable	2706	2737
	2/ Gloves, impermeable coverall	6.97E-03	70	not applicable	85	116
metaSPC 9: PT3: CIP disinfectants used in milking parlour- Iodine						
Combination of exposures via pouring and pumping is and considered covered by the local risk assessment.						

metaSPC 10: PT3 Concentrated teat disinfectants – Iodine						
Scenarios [1, 2, 3, 4]	Tier 1/ none	1.29E-02	129	140	155	186
	Tier 2/ Gloves	3.90E-03	39	50	65	96
metaSPC 11: PT3 RTU teat disinfectants – Iodine						
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	1.16E-02	116	125	140	171
	Tier 2/ Gloves	3.65E-03	37	46	61	92
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	1.80E-03	18	32	47	78
	Tier 2/ Gloves	1.80E-04	2	16	31	62
metaSPC 12: PT3 RTU teat disinfectants – Iodine						
Scenarios [1.1, 2.1, 3, 4]	Tier 1/ none	1.58E-02	158	177	198	222
	Tier 2/ Gloves	3.39E-03	34	53	68	99
Scenarios [1.2, 2.2, 3, 4]	Tier 1/ none	2.46E-03	25	53	68	99
	Tier 2/ Gloves	2.46E-04	2	31	46	77

[1] Values derived from post-application use are included for scenarios that include post-application teat-disinfection uses, and is non-applicable for use on surfaces or for skin disinfection.
[2] Total milk intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) and the background milk value of 200 µg/L (EFSA 2013), considering 0.45 L intake for an adult.
[3] Total dietary intake is the sum of the estimated additional intake resulting from the transfer into milk following teat disinfection (based on O'Brien) only applicable for scenario 1 and 2, the background milk value of 200 µg/L (EFSA 2013) and 185 µg/d for adult or 96 µg/d for toddler based on UK data (2008) considering 0.45 L intake for an adult.

Calculation sheet is included in annex 3.2. It is noted that besides the worst case, all worst cases per metaSPC are included.

It can be noted that for the combined scenario of metaSPC 7 and metaSPC8 (PT3-use) the **%** UL (0.01 mg/kg bw/day) due to biocidal use + total dietary intake is resp. 110% and 116% with gloves and impermeable coverall. This exceedance of the UL would normally not be acceptable. However, the following arguments support to accept this exceedance in this specific case:

- Exposure from animal house disinfection should not be carried out at high frequency, i.e. not more than 3 times per month
- The animal house disinfection as such results in just 45% of the UL, the rough dietary exposure estimate adds the higher amount of 65%.
- In spite of slightly exceeding the UL value, there are still high margins to doses where marginal and not clinically adverse effects were observed in adult humans (1700-1800 µg Iodine/day for adults, see footnote 1 to table underneath section heading 2.2.6.3.2.2.).

Consequently, the risk for these professional and dietary combined exposures is considered acceptable, in case frequency of application in animal housing spraying is low, not more than 3 times per month. Therefore the following RMMs needs to be included for

metaSPC7 and 8 and when these are taken into account the exposure due to use for animal housing disinfection is considered acceptable:

- Due to potential concern for human health the professionals must not carry out animal house disinfection more than 3 times per months. These professionals should not use Iodine products for additional purposes. Only use one kind of Iodine-containing product per day.

Conclusion

Risk from the professional use of products included in metaSPC1-12 are acceptable when wearing the following RMM:

metaSPC1 and 10 PT3:
- For mixing an loading of the product: Wear chemical resistant gloves and eye/face protection.
- For manual spraying application: Wear chemical resistant gloves.

metaSPC2, 5, 11 en 12, PT3:
- For manual spraying application: Wear chemical resistant gloves
- For manual dipping application: no PPE is necessary for safe use.

metaSPC3 PT3:
- For manual spraying application on cows and sows: Wear chemical resistant gloves.

metaSPC4 PT3:
Teat disinfectant
- For manual spraying application: Wear chemical resistant gloves
- For manual dipping application: no PPE is necessary for safe use.

Skin disinfectant
- For manual spraying application on cows and sows: no PPE is necessary for safe use.

metaSPC6, PT3:
- For manual spraying application on cows and sows: Wear chemical resistant gloves.

metaSPC7 PT3:
- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall and eye/face protection.
- During spraying of the product: Wear chemical resistant gloves and an impermeable coverall.

Furthermore, the following RMM needs to be added:

- Due to potential concern for human health the professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes. Only use one kind of Iodine-containing product per day.

metaSPC8 PT3:
- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coverall and eye/face protection.
- During spraying of the product: Wear chemical gloves and impermeable coverall.

Furthermore, the following RMM needs to be added:

- Due to potential concern for human health the professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes. Only use one kind of Iodine-containing product per day.

metaSPC9 PT4:

- During pouring and pumping of the concentrated product: Wear chemical resistant gloves, coated coverall and eye/face protection.

Additional conclusions on BPF

For the professional use for teat disinfection on cows and skin disinfection on cows, the use PPE for either use is necessary to conclude safe use. Furthermore, for the professional use for teat disinfection and the disinfection of animal housing, the use PPE or PPE/RPE for either use is necessary to conclude safe use.

Based on the %UL for combined exposure, taking into account iodine from dietary exposure per use, products in this BPF for the exposure scenarios cannot be used at the same time or otherwise would exceed the UL, which is considered not acceptable.

Therefore, the following risk mitigation measure needs to be included:Only use one kind of Iodine-containing product per day.

Risk for non-professional users

Non-professional users are not expected to use products from the BPF. They can be exposed (secondary exposure) via residues in food. This is described in the paragraph "Risk for consumers via residues in food".

Risk for the general public

Non-professional users are not expected to use products from the BPF. They can be exposed (secondary exposure) via residues in food. This is described in the paragraph "Risk for consumers via residues in food".

Risk for consumers via residues in food

The risk for consumers via residues in food concerns both professionals and general public (secondary exposure).

Some scenarios are theoretically envisageable but not relevant because not realistic or covered by the main scenario of residues in milk following teat disinfection. Indeed the exposure to residues in meat following use of teat disinfectants is covered by the exposure to residues in milk following the same use according to the CAR of iodine. The disinfection of animal housings takes place maximum 13 times per year according to the ESD for PT3 "veterinary hygiene biocidal products" so the exposure is very occasional (contrary to the 365 days of exposure for teat disinfection of cows). Furthermore, disinfection of animal housings takes generally place between batches, meaning that animals joining the slaughterhouses are not exposed to iodine of products used for animal housings disinfection. Disinfection of skin and hooves is also occasional and concern new animal

joining the herd or farrowing animals. Disinfection of udders (new cows joining the herd) is not expected to be concomitant with teat disinfection. Disinfection in food industry and disinfection of milking installations and milking tanks are followed by a torough rinsing minimising the risk of residues.
For products used in PT4 (food industry and disinfection of milking parlours systems) exposure of animals (primary or secondary) is not expected, as disinfection are followed by a torough rinsing minimising the risk of residues. A residue testing has been performed and iodine could not be quantified after rinsing because below the limit of quantification. This testing is added in IUCLID part 8 and added in the reference list.

Note eCA: dietary exposure is discussed in various human health working group meetings and WebEx meetings for eCA evaluating iodine based union authorisations application. For the exposure to residues, the O'Brien study can be used. The assumptions that could be considered for the exposure to residues via milk were that needs to be considered are included below:

- Exposure in accordance to intended use (WGIII 2017). Therefore, the indicated worst case scenarios are taken into account, based on 0.5% available iodine from metaSPC5. Other metaSPC are also calculated as this information was necessary for calculating the professional exposure due to use. All calculations are included in Annex 3.2; residues.
- For exposure to residues the following was concluded by eCAs from iodine based union authorisation applications (Secure Webex meeting (3-10-2017)): "The expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable". However, as the residue exposure should be in line with the intende use, and as the amount of product is 5 ml per cow, independent whether the application is performed manually or auhtomatically, the worst case is automatic application and 3 times exposure. Therefore the exposure based on the O'Brien study, which was applied twice needs to be recalculated. Taking into account a density of 1.03 kg/L for whole milk (Ullmanns's Food and Feed, 3 Volume set. (Elvers, B. (2017). 1st ed. Weinhem, Germany: Wiley-VCH, page 344).
- 50% reduction due to bulking of milk is not allowed (WGII 2017).
- 27% reduction due to pasteurisation of the milk is not allowed. (WGII 2017)
- At WGIV 2017 it was agreed that for daily milk consumption to use 0.45 L/day for adults (EFSA PRIMo version 2, based on highest mean for Dutch populations) and 0.46 L/day for infant/toddlers (EFSA PRIMo version 2, based on highest mean for French population).
- For the calculations information from the O'Brien study was used. The O'Brien study assessed the effect of a teat disinfection product is used, based on 0.5% available iodine on the total iodine content in milk. Therefore, the measured residues in milk are from the O'Brien study does not need to be corrected for the worst case of the BPF of CIDLINES, which is included below in the table. However, on metaSPC level as they include lower available iodine concentrations, these values were corrected. Furthermore, as products included in the BPF are used for post-application only. Consumers are exposed to residues of iodine due to various sources. The inclusion from other sources in the consumer risk assessment was discussed at WGIV, and the following was concluded:
  Iodine exposure from all sources will be included in the assessment.
  The assessment will include exposure to iodine coming from:

1. Teat treatment
2. Teat treatment + background from milk (= total milk intake)
3. Teat treatment + background from milk + dietary intake from other sources (= total dietary intake)

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

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/d) and infants/toddlers (200 µg/d) and depicted in the table below. Intakes which exceed the respective UL are highlighted in red in the table below. Calculations are included in annex 3.2 (residues). It is noted that only the worst-case is shown in the table below, however, all calculations are included in the provided document as included in the annex.

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

Comparison of estimated daily iodine intakes compared to upper limit of post-milking teat-disinfection by manual dipping/spraying, based on the worst case of 0.5% available iodine. Intakes which exceed the UL are highlighted in red in the table below.

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

3x post-milking		
Intake from milk due to teat treatment	183 31	187 94
Total milk intake*	273 46	279 140
Total dietary intake**	458 76	375 188

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

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

Calculations are included in annex 3.2 (Cidlines residues). It is noted that only the worst-case is shown above in the table, however, all calculations are included in the provided document as included in the annex.

Conclusion: Post-milking teat-disinfection

For adults, the estimated daily intake of iodine resulting from biocidal product use is maximally 31% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 46% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 76% of the UL.

For toddlers, the estimated daily intake of iodine resulting from biocidal product use is maximally 94% of the UL. When background values for iodine in milk is added, the iodine intake from milk consumption is maximally 140% of the UL. Finally, a total dietary intake of iodine resulting from milk consumption and from other dietary sources lead to maximally 188% of the UL.
For all metaSPCs the UL for toddlers is exceeded when taken into account teat disinfection and dietary intake.

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

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

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

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

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

1. Feed supplementation
2. Food and salt supplementation
3. Dietary supplements

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

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

   Several studies have been conducted to experimentally determine the contribution to iodine levels in milk from use of iodine containing teat dips [Conrad & Hemken, 1978; Hemken, 1980; Sheldrake et al. 1980; Hemken et al, 1981; Galton et al.,

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

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

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

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

reached what would be considered acceptable for exceedance, and also there was no support to change the limit value at this stage. Therefore, the limit value should be considered during active substance renewal.

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

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

Note eCA: scenario number 2-5 is added after commenting phase and discussion in WG.
Additional notes:

- Scenario 2 – Udders of cows and of pigs will be disinfected a few days before and one day after respectively calving and farrowing. Milk will be used for newborns and the mother will not go the the slaughter house. Therefore, no exposure to residues due to this use is envisaged. Additionally, the udder disinfection will be equal to the teat disinfection scenario, therefore covered by the assessment for teat disinfection.
- Scenario 3 – dietary exposure will be addressed for humans by indirect exposure by eating livestock from animal treated housing. The livestock exposure is included in section: risk assessment for animal health.
- Scenario 4 – dietary exposure will be addressed for humans by indirect exposure to food that has been in contact to treated surfaces.
- Scenario 5 – dietary exposure will be addressed for humans by indirect exposure to food from treated CIP installations or to food from treated milking equipment

Scenario 3: Surface disinfection in animal housing

Livestock are not present when the animal housing is dinfected, therefore only indirect exposure of animals is determined for products included in metaSPC 7 and 8.
Worst case exposure assessment for the animals is performed and included in section: risk assessment animal health. In summery, for cows and pigs the indirect exposure via rubbing, eating of contaminated food, licking of sufaces is taken into account. For laying hens the consumption of contaminated food and contaminated flies is taken into account.

As the calculated residues exposure of 203 µg/d and 36 µg/d for respectively adults and toddlers are well below their UL when based on worst case assumptions (i.e. 600 µg/d

and 200 µg/d), no adverse health effects are expected after indirect exposure to residues by eating food from animal origin from animal treated use included in metaSPC 7 and 8.

Scenario 4: Surface disinfection in professional kitchens and food industry

For products used in PT4 (food industry and disinfection of milking parlours systems) exposure of humans (primary or secondary) of products included in metaSPC7 and 8 is not expected, as disinfection are followed by a torough rinsing minimising the risk of residues.

A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.
Tested formulation for metaSPC8 is equal to the max. concentrations of the co-formulants which are max. in iodine equivalents and in phosphoric acid included this metaSPC.
A 10% diluted product is used for the test, which is worst case to the in-use dilution of products included in metaSPC7 and 8 which are used in the food industry.

As the residues found on the inox surface is below the quantificiation limit of analytical method (3ppm equal to 0.0003%), no adverse health effects are expected after indirect exposure to residues by surfaces treated with products included in metaSPC7 and 8.

Scenario 5: Surface disinfection from CIP installations and milking equipment

For products included in metaSPC9 to be used in CIP installations and milking equipment (food industry and disinfection of milking parlours systems) exposure of humans is not expected, as disinfection are followed by a torough rinsing minimising the risk of residues.
A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.

A residue testing has been performed and is included in the confidential annex, section 11 and added in the reference list.
Tested formulation for metaSPC8 is equal to the max. concentrations of the co-formulants which are max. in iodine equivalents and in phosphoric acid included this metaSPC.
A 10% diluted product is used for the test, which is worst case to the in-use dilution of products included in metaSPC9 which are used CIP installations in the food industry or in milking equipment.

As the residues found on the inox surface is below the quantificiation limit of analytical method (3ppm equal to 0.0003%), no adverse health effects are expected after indirect exposure to residues by CIP installations and milking equipment treated with products included in metaSPC9.

As scenario 5 does not lead to additional iodine exposure, no combined assessment of scenario 1 (milk from teat disinfection) and scenario 5 is considered necessary.

Risk assessment for animal health

Reference values to be used in Risk Characterisation

$UL_{farm\text{-}animals}$ = tolerable upper intake (for all time frames) [1]	Scientific Opinion on the safety and efficacy of Iodine compounds (E2) as feed additives for all species; EFSA Journal 2013;11(2):3101	10 mg/kg feed = 0.4 mg/kg bw day for cattle, calf, sheep, goat 0.7 mg/kg bw day for

		laying hen
Dermal absorption rate	Based on in vitro studies and conclusion for human dermal absorption.[2]	12%

[1] EFSA Journal 2013;11(2):3101 reviewed available data for animal health and concluded (see section 3.1.2) that currently established maximum Iodine content in feed (10 mg/kg) coincides with the upper tolerated level in chickens, pigs as well as dairy cows. The eCA considered this value indicative also for sheep and goats. Furthermore, the EFSA reference includes a reference to Meyer et al 2008 (Livestock Science, 115, 219–225), a study with fattening 34 growing fattening bulls of the "German Holstein" breed, in the range from 223 to 550 kg body weight, so this includes calf to youg adult exposure. Dry matter intake and daily weight gain were not significantly influenced by Iodine concentration of 8 mg/kg dry weight feed. Though the thyroid weight was significantly increased at this top concentration level, the eCA considered this concentration level useful as an indicative limit value for the single calf exposure expected from animal house disinfection (the calfs grow to adult before potential next stable disinfections). Considering the feed consumption (26kg for dairy cow, 8 kg calf, 3 kg for sheep, 3 kg for pig, 2.8 kg for lacting goat, 0.13 kg laying hen) and an UL of 10 mg Iodine/kg food and the body weight of these animals (650 kg for dairy cow, 200 kg for calf, 100 kg for fattening pig and 650 kg for breeding pig, 75 kg for sheep, 70 kg for lacting goat, 1.9 kg for laying hen) this results in an UL of 0.3 mg/kg bw day for fattening pig and 0.23 mg/kg bw day for breeding pig, 0.4 mg/kg bw day for cow, calf, sheep, goat and 0.7 mg/kg bw day for laying hen.
[2] see section on animal exposure.

Calculations are included in annex 3.2 (Cidlines animal exposure).

Teat-disinfection

	Iodine uptake via teat disinfection	Iodine uptake via Iodine supplemented feed	Total exposure	UL farm- animals	% of UL farm- animals	**Acceptable (yes/no)**
	mg/kg bw/day	mg/kg bw/day	mg/kg bw/day	mg/kg bw day	%	
Scenario [1a] dairy cow	0.19	0.002	0.19	0.38	51	yes
Scenario [1b], sheep	0.20	0.019	0.22	0.4	55	yes
Scenario [1c], lacting goat	0.20	0.021	0.22	0.4	55	yes
Scenario [1d] buffalo = bw of beef	0.20	0.003	0.20	0.4	51	yes

*dermal absorption rate of 12% assumed as for human (WGVII 2018)

Local effects

MetaSPCs including use for teat disinfection can be devided in concentrated and RTU products. None of the RTU products are classified for irritating effects (i.e. metaSPC2, 4, 5,

6, 11 and 12). The concentrated products are classified as dangerous for the eyes (i.e. H318, metaSPC 1 and 10), however, the diluted products do not need to be classified for irritating effects for skin or eyes. Therefore, no adverse effects due to local effects are expected for the animal due to the use of products for teat disinfection included in the BPF.

Conclusion teat disinfection

The exposure assessment according to the DRAWG draft guidance for biocides was carried out for the post milking spray application (considering the worst case meta SPC6, maximal total iodine concentation 1.8%) and this is representative also for the post milking dipping application included in metaSPC 1-5, 10-12 (total iodine 0.44 – 1.45%, see detail calculations worst case concentrations, annex 3.2). Furthermore, exposure was corrected in Tier 2 with a dermal absorption rate of 12% assumed as for human (WGVII 2018) was taken into account. This value for animal exposure was discussed and agreed upon at WGVII 2018 for a comparable application. The exposure estimate for dairy cow, sheep, lacting goat and buffalo are all below the resp. animal UL, and therefore considered acceptable.

The resulting total exposure estimates for dairy cows are beyond the human UL in terms of mg/kg bw day but below the UL for farm animals as derived from the EFSA 2013 opinion on the safety and efficacy of Iodine compounds (E2) as feed additives.

Within this opinion it was also concluded that the Iodine level in edible tissues/products is generally found to be highest in milk and not in meat. In line with this also EMEA (European Agency for the Evaluation of Medicinal Products) concluded within their summary report on Iodine-containing products used for veterinary medicine, that only small increases in serum Iodine concentration have been found after teat dipping indicating that the procedure has a negligible effect on tissue Iodine concentrations. In addition, Iodine-based teat-disinfection products have a long history as safe veterinary hygiene and medicinal products.

Consequently the risk from post-milking teat disinfection within meta SPC 1-6, 10-12 is considered acceptable also with regard to animal health protection.

Skin-disinfection

Use for skin disinfection is included in metaSPC3,4 and 6. The product is to be used on the skin of udders of dairy cows before and after calving or on skin of udders of sows before and after farrowing.
The exposure of cows before and after calving is considered covered the exposure of cows calculated for teat disinfection before and after milking, as it concerns the same species and the amount of product used in the same as for teat disinfection.
The exposure of sows however is considered not covered by cow teat disinfection, as the amount of product is twice as much on a daily basis compared to the use on cows for teat disinfection (i.e. 20 ml to be used on sows once a day v.s. 5 ml per milking event, is 10 ml to be used on cows on a daily basis) and a cow is much larger compared to a breeding pig (650 kg dairy cow v.s. 260 kg).
The teat disinfection calculations are fully in line with a previous comparable dossier (discussed in WGVII 2018), and the calculations were only adapted in line with information on this dossier.
For the teat disinfection calculations, 1.2 ml remains on the teat. Therefore, for the exposure of the udder of the sow, it was assumed that 20 ml/10 ml x 1.2 = 2.4 ml remains on the udder after treatment.

	Iodine uptake via skin disinfection	Iodine uptake via Iodine supplemented feed	Total exposure	UL farm- animals	% of UL farm- animals	**Acceptable (yes/no)**
	mg/kg bw/day	mg/kg bw/day	mg/kg bw/day	mg/kg bw day	%	
Scenario [1a] fattening pig	0.052	0.15	0.20	0.30	67	yes
Scenario [1b] breeding pig	0.020	0.12	0.14	0.23	59	yes

*dermal absorption rate of 12% assumed as for human (WGVII 2018)

Local effects

MetaSPCs including use for skin disinfection are not classified for irritating effects (i.e. metaSPC3, 4 and 6). Therefore, no adverse effects due to local effects are expected for the animal due to the use of products for skin disinfection included in the BPF.

Conclusion skin disinfection

The exposure assessment according to the DRAWG draft guidance for biocides was carried out for the skin disinfection of udders of cows or sows before delivery (considering the worst case meta SPC6, maximal total iodine concentation 1.8%) and this is representative also for the use for skin disinfection included in metaSPC 3 and 4 (total iodine 0.5 – 1.45%, see detail calculations worst case concentrations, annex 3.2). Furthermore, exposure was corrected in Tier 2 with a dermal absorption rate of 12% assumed as for human (WGVII 2018) was taken into account. This value for animal exposure was discussed and agreed upon at WGVII 2018 for a comparable application. The exposure estimate for fattening pig and breeding pig are below the resp. animal UL, and therefore considered acceptable.

Consequently, the risk from skin disinfection within meta SPC 3, 4 and 6 is considered acceptable with regard to animal health protection.

Animal housing assessment

	Exposure via animal house spraying [mg/kg bw day]	UL farm-animal [mg/kg bw day]	% UL	**Acceptable (yes/no)**
Tier 1				
Scenario 2a calf	1.02	0.40	255	no
Scenario 2b: laying hen	0.214	0.68	31	yes

Scenario 2c: dairy cattle	0.121	0.38	32	yes
Scenario 2d: pigs	1.167	0.30	389	no
Tier 2*				
Scenario 2a calf	0.250	0.40	63	yes, see argumentation included in the conclusion
Scenario 2b: laying hen	0.170	0.68	25	yes
Scenario 2c: dairy cattle	0.117	0.38	30	yes
Scenario 2d: pigs	0.373	0.30	124	yes, see argumentation included in the conclusion

*dermal absorption rate of 12% assumed as for human

Combined assessment

	via animal house spraying [mg/kg bw day]	via supplemented feed [mg/kg bw day]	Via teat dis-infection	total exposure [mg/kg bw day]	$UL_{farm-animal}$ [mg/kg bw day]	% UL	**Acceptable (yes/no)**
Tier 1							
Scenario 2a calf	1.02	0.20	n.a.	1.22	0.40	305	no
Scenario 2b: laying hen	0.214	0.34	n.a.	0.56	0.68	81	yes
Scenario 2c: dairy cattle	0.121	0.19	0.066	0.38	0.38	99	yes
Scenario 2d: pigs	1.167	0.15	n.a.	1.32	0.30	439	no
Tier 2*							
Scenario 2a calf	0.250	0.20	n.a.	0.45	0.40	113	yes, see argumentation included in the conclusion
Scenario 2b: laying hen	0.170	0.34	n.a.	0.51	0.68	75	yes
Scenario 2c: dairy	0.117	0.19	0.008	0.32	0.38	82	yes

cattle							
Scenario 2d: pigs	0.373	0.15	n.a.	0.52	0.30	174	yes, see argumen teation included in the conclusi on

*dermal absorption rate of 12% assumed as for human

	Exposure of through by animal house spraying [mg/kg bw day]	UL farm-animal [mg/kg bw day]	% UL	**Acceptable (yes/no)**
Tier 1				
Scenario 2a calf	2.0	0.40	502	no
Scenario 2b: laying hen	n.a.			
Scenario 2c: dairy cattle	2.0	0.38	530	no
Scenario 2d: pigs	2.4	0.30	802	no

*oral absorption rate of 100% assumed as for human

The calculation sheet is included in Annex 3.2; cidlines animal exposure.

Local effects

MetaSPCs including use for animal house disinfection are classified for irritating effects (i.e. metaSPC7: H318 - Causes serious eye damage, and metaSPC8; H315: Causes skin irritation and H318- Causes serious eye damage). However,the product is diluted before application, and the diluted products do not need to be classified for irritating effects for skin or eyes. Therefore, no adverse effects due to local effects are expected for the animal due to the use of products for animal housing disinfection included in the BPF.

Conclusion animal house spraying

The exposure assessment for animal house spraying application according to the DRAWG draft guidance for biocides was corrected within tier 2 for a dermal absorption rate of 12% as for humans. This value for animal exposure was discussed and agreed upon at WGVII 2018 for a comparable application. The exposure-estimate for laying hen and dairy catlle are below the resp. animal UL, and therefore considered acceptable. However, the exposure of both calves and pigs are exceeding their respective animal UL. The exceedance is similar as discussed for a comparable application discussed at WGVII 2018. In the WG it was concluded that the exceedance was acceptable, as animal stables are not disinfected frequently, resulting in a low frequency of exposure (once per lifetime) of calves and pigs.

Calculations on animal exposure due to disinfection of the trough show no safe use for calves, laying hens, dairy cattle and pigs. Therefore, the following RMM needs to be included: Feeding troughs must be covered during application. Considering this instruction, the animal exposure via their trough is considered mitigated.

Risk assessment for the environment

A. EFFECTS ASSESSMENT ON THE ENVIRONMENT

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance. The following values has been used in the risk assessment. As iodine is a natural occurring substance, PECs were also compared with the background concentrations.

STP:

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

Iodide and iodate: no PNEC derived in the CAR (2013) on iodine.

Aquatic compartment:

Iodine: $PNEC(I_2)_{aquatic}$ = 0.59 µg /L
Iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg /L
Iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg /L

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

Terrestrial compartment:

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

Information on background levels:

Background concentration of iodine in the environment (CAR, 2011 on iodine)	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L
Marine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 98 mg/kg_{dwt} (corresponding to 0.4 - 18 mg iodine/kg_{wwt} with extremes up to 86 mg/kg_{wwt}) depending on soil types and locations. Highest concentrations are found in peaty soils (18.7-98.2 mg/kg dwt). Concentrations in sandy

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

Further Ecotoxicological studies

Summary table - Further ecotoxicological studies

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Assessment for endocrine disrupting properties

As discussed in Section 2.2.6.1, the Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

The products were not tested for potential endocrine disruption properties. The products contain the active substances iodine and PVP-iodine, and various co-formulants (see confidential annex).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. Iodine (and PVP-iodine) is included in the list of active substances for which an early review was triggered in CA-80, September 2018 (CA document on the subject: Implementation of scientific criteria to determine the endocrine-disrupting properties of already approved active substances (CA-March18-Doc.7.5.a-Final - EDs approved active substances)), because this active substance is identified as possible ED and the renewal process for this substance does not take place before the end of 2020. Therefore, identification of the active substance as having ED properties should be re-considered following the outcome of the EU discussions.

For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- The United States EPA
- The United Nations Environment Program (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
- The list on Endocrine Disrupting Chemicals, Final Report (December 2017). Danish Centre on Endocrine Disrupters (http://cend.dk/files/DK_ED-list-final_2018.pdf)

- List of Chemicals suspected of having endocrine disrupting effects, as part of the Strategic Programs on Environmental Endocrine Disruptors ’98 (SPEED ’98). Ministry of the Environment, Government of Japan (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.html)

As discussed in the confidential section, an alert is identified by the eCA for two co-formulants. However, the outcome of EU discussions should be awaited for these two co-formulants.

None of the other co-formulants triggered an alert for potential endocrine disruption properties (see also the assessment included in the confidential annex).

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

Disinfection of teats, animal skins, stables, and milking machines predominantly results in emission to soils via liquid manure to soils or to surface water via the municipal sewer. Exposure to air during application is not relevant due to the low vapour pressure of the active substance. However, considering that most farms are not connected to the municipal sewer, waste water is often released to the manure depot instead, although waste water that is free of animal manure and milk may be collected and brought to the sewer manually, e.g. via tankers. If present, residues may be released to individual sewage treatment plants as well when equipment is for instance rinsed above sinks.

Application in the food and feed industry (PT04) results in emission to the municipal sewer. After purification the STP's effluent is discharged to surface water and subsequently distributed over water and sediment. Where allowed, sewage sludge is applied as a soil fertiliser, resulting in a secondary emission to soils and groundwater. Emission to soils via air is less likely as iodine species are not expected to be volatile.

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Leaching behaviour (ADS)

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Testing for distribution and dissipation in soil (ADS)

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Distribution

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Dissipation

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Testing for distribution and dissipation in air (ADS)

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Summary table of half-lives identified relevant metabolites and transformation products in air

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Dissipation

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

The products of the BPF are not expected to be sprayed near to surface waters.

Acute aquatic toxicity

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Chronic aquatic toxicity

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Measured aquatic bioconcentration

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

Estimated aquatic bioconcentration

All ecotoxicology data is found in the CAR on iodine. No further investigation has been done on active substance.

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

The products of the BPF are not expected to be sprayed outside and large scale formation of dust is not expected.

B. EXPOSURE ASSESSMENT

General information

Products of the BPF are used in PT3 and PT4:

Assessed PT	PT 3
Assessed scenarios	Scenario 1: Disinfection of teats (metaSPC 1, 2, 4, 5, 10, 11, 12) Scenario 2: Disinfection of animal housings (metaSPC 7 and 8) Skin disinfection are also claimed for metaSPC 3, 4 and 6. Skin disinfection concerns the disinfection of skin of udder of cows one day before and one day after calving (cows give birth once per year) with one spray per teat (about 4.8 mL of product per cow). The last use concerns the disinfection of the udder of the sows once, 1 day before and once, 4 days after farrowing (15-20 mL of product per treatment). Regarding the occasional use of skin disinfectant and the low quantity of product necessary per day in comparison with teat disinfectants used every day or stables disinfectant where high quantity of product are necessary, environmental exposure due to disinfection of skin (metaSPC 3, 4, 6) is considered as covered by the metaSPC 2 for dairy farms and 8 for sows farms.
ESD(s) used	Emission Scenario Document for Product Type 3: Veterinary hygiene biocidal products, 2011 Technical agreement on biocides (TAB) version 2.0, agreement ENV-168. Scenario 1: scenario for non-medicinal teat dips on metaSPC 2 (worst-case 0.78% total iodine) page 23 ESD PT3 Scenario 2: scenario for disinfection of animal housings (page 13 ESD PT3)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	• Scenario 1A/2A: release in the slurry/manure or in waste water released in slurry/manure: Soil, Groundwater, Secondary poisoning terrestrial food chain, Surface water, Sediments, Secondary poisoning aquatic food chain • Scenario 1B/2B: release in the waste water linked to a STP: STP, Surface water, Sediments, Secondary poisoning aquatic food chain, Soil, Groundwater,

	Secondary poisoning terrestrial food chain
Groundwater simulation	Calculated based on ESD and ECHA – Guidance on the Biocidal Products Regulation: Volume IV Environment-Assessment and Evaluation (Parts B+C) Version 2.0 October 2017.
Confidential Annexes	Yes – annexes are in the Part 9 of the IUCLID 5.6.0.
Life cycle steps assessed	Scenario 1 & 2: Production: No Formulation No Use: Yes Service life: No
Remarks	According to CAR of Iodine, fraction of iodine retained in sludge from STP is 20% and iodine released in water from STP is 80%. According to the CAR of iodine, Kpsoil =5.8 cm^3/g, Kpsusp=220 cm^3/g. Values are used in the EUSES simulations.

Assessed PT	PT 4
Assessed scenarios	Scenario 1: Disinfection of surfaces in food industry (metaSPC 7 and 8) Scenario 2: CIP disinfection in food industry (metaSPC 9) Scenario 3 CIP disinfection in milking parlours system (metaSPC 9)
ESD(s) used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, 2011 Scenario 1: IHO 2006 table 10 ESD PT4 Scenario 2: Bakker scenario (ESD PT4) Scenario 3: Baumann scenario (ESD PT4)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: Average consumption
Distribution in the environment	Scenario 1, 2, 3: release in the waste water linked to a STP: STP, Surface water, Sediments, Secondary poisoning aquatic food chain, Soil, Groundwater, Secondary poisoning terrestrial chain. •
Groundwater simulation	Calculated based on ESD and ECHA – Guidance on the Biocidal Products Regulation: Volume IV Environment-Assessment and Evaluation (Parts B+C) Version 2.0 October 2017.
Confidential Annexes	Yes – annexes are in the Part 9 of the IUCLID 5.6.0.
Life cycle steps assessed	Scenario 1, 2 & 3:

	Production: No Formulation No Use: Yes Service life: No
Remarks	According to CAR of Iodine, fraction of iodine retained in sludge from STP is 20% and iodine released in water from STP is 80%. According to the CAR of iodine, Kpsoil =5.8 cm^3/g, Kpsusp=220 cm^3/g. Values are used in the EUSES simulations.

Emission estimation

Formulation phase takes place in the production site of CID Lines N.V. (Belgium). Waste water is collected in a buffer tank where pH is controlled continuously and water is purified with an aerobic biological treatment, followed by a physical-chemical treatment and a filter press. Effluents are collected in a buffer tank where pH as well as other parameters such as metals contents are controlled before release in the environment. Sludge are treated by an external company. Treatment of wastes is compliant with the current License of CID Lines N.V. allocated by the Belgian Department of Environment, Nature and Energy.

Risk assessment including classification and labelling was made for the productfamily that resulted in the highest emission and based on the total iodine contents of the product including iodine from possible co-formulants. No correction were made for density in line with the assessment on efficacy, the density may vary within a meta-SPC, and corrections as only a marginal effect on the final risk ratios. The iodine concentrations applied are presented below. None of the co-formulants fulfils the criteria for substance of concern as specified in the guidance part C. Consequently, only iodine was considered in the environmental risk assessment.

PT3 – metaSPC 1, 2, 3, 4, 5, 6, 7, 8, 10, 11, 12

General

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

environmental concentrations (PECs) based on the nitrogen emission standards are presented in the current PAR.

According to the CAR on iodine (I_2), iodate (IO^{3-}) may be considered to be the dominant chemical form of iodine in the soil solution under aerobic non-flooded soil conditions, while iodide (I^-) appears mainly under anaerobic conditions. In surface water, however, both species may appear depending on the acidity (pH) and oxygen concentrations (redox) of the receiving fresh water body. In general iodate is the dominant species in water close to oxygen saturation, while iodide is present in water low in oxygen contents. Predicted environmental concentrations were therefore calculated assuming no transformation (100% iodine) and 100% transformation into iodine or iodate. Limited information on the behaviour of iodate and iodine in environmental compartments is available. Therefore, the physical-chemical properties for iodine were applied to these two transformation products as well.

The PEC's as calculated with the ESD represent the concentration after one manure application on arable land and one on grassland (Predicted Initial Environmental Concentrations, PIEC). However, agricultural soils are fertilised repeatedly and iodine may consequently accumulate in soils after successive years of manure applications. Therefore, the concentrations presented in the current assessment report are the concentrations after ten years, i.e. ten manure applications on arable land and forty on grassland. Concentrations in soils after ten years were calculated according to the addendum for PT18 (insecticide in stables) including the latest agreements (no-manure time was increased from 206 to 365 days).
Although iodine being an element does not degrade, it disappears from soils between two subsequent manure events due to leaching. The leaching rate constants and resulting PECs were calculated according to the guidance by applying an experimentally-derived solid-water partitioning coefficient for soils of 5.8 L/kg and the active substance's physical-chemical parameters as presented elsewhere. The corresponding half-lives for leaching from the topsoil layer are 2571 d in arable land (20 cm) and 643 d in grassland (5 cm).

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

Scenario 1: Disinfection of teats

Scenario 1A describes the disinfection of teats with products of metaSPC 1, 2, 4, 5, 10, 11, 12 with release in the slurry/manure or in waste water released in slurry/manure: Soil, Groundwater, Feed, Surface water, Sediments, Feed.

Scenario 1B describes the disinfection of teats with products of metaSPC 1, 2, 4, 5, 10, 11, 12 with release in waste water linked to a Sewage Treatment Plant.

Products of metaSPC 2 contain up to 0.78% of total Iodine (ready-to use). Therefore assessment of products from metaSPC 2 covers the assessment of teat disinfectants in other meta SPCs as the use concentrations in these SPCs are lower.
Results of assessment of metaSPC 2 are therefore presented.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1A and 1B: Disinfection of teats			
Application rate of biocidal product *per animal per treatment*	5 mL	ml/cow	Worst-case value according to the Consumption study presented in IUCLID.
Concentration of active substance in the product	8.41	g/l	Taking in account the worst-case density of 1.078
Frequency of application per day	3	-	The ESD assumes two milking events per day. However, cows are milked 3 times a day in milking robots
Fraction of active released in manure/slurry or in waste water	0.5	-	Cf guidance ESD for PT3
Number of days of lactation period	300	d	Cf guidance ESD for PT3

Emission to the STP, grassland, and arable land was calculated according to the ESD by applying the default parameters. The results are summarised in the table below.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	5. 18E-03 kg iodine-iodide/d 7.16E-03 kg iodate/d	For dairy cattle release to the sewer was set equal to release to the manure ($F_{stp}=F_{manure}=0.5$)
emission to grassland ($Q_{ai,\ grass}$)	0.334 kg iodine-iodide/manure application 0.462 kg iodate/manure application	
emission to arable land (Q_{air_ar})	1.34 kg iodine-iodide/manure application	

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
	1.85 kg iodate/manure application	

Scenario 2: Disinfection of animal housing

Scenario 2A describes the disinfection of animal housings with products of metaSPC 7 and 8 with release in the slurry/manure or in waste water released in slurry/manure. Scenario 2B describes emission to the municipal sewer. Emission to the sewer is only calculated for those stable for wich a fraction to the sewer is included in the ESD. This concerns most of the stables for poultry. There is no emission to the sewer for dairy cows, beef, and pigs.

Products of metaSPC 7 and 8 contain the same content of iodine in pure product and are diluted the same way to allow a final concentration of 0.035% of iodine. The results are of exposure are the same for both metaSPC 7 and 8. 18 categories of animals are reported in the ESD guidance for PT3 Veterinary hygiene biocidal products. The worst case results are presented.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2A and 2B: Disinfection of stables			
Application rate of working solution	40	ml/m²	No default values are available. The SPC however contains clear instructions about fluid consumption in order to prevent unnecessary discharge of superfluous fluids to the environment. The applied dosing rate will not influence the products' efficacy.
AREA to be disinfected	Floor area, slatted area, wall and roof area and "other inside areas"	m²	Depending on the animal category. See the ESD (PT03) for details.
Concentration of active substance in the working solution (expressed as total	0.065	% w/w	

iodine)			
Frequency of application	1 to 13/y	-	Depending on the animal category. See the ESD (PT03) for details.
Fraction of active released in manure/slurry	0.3 to 0.5	-	
Fraction of active released in waste water	0.3 to 0.5		

In accordance to TAB agreement ENV-168 (TAB 2.0) the fraction to the sewer has been added to the fraction to the manure for indirect release to soils. This only concerns the stable types for which a fraction to the sewer is presented in the ESD.

Calculations for Scenario [2]

Emission to the STP, grassland, and arable land was calculated according to the ESD by applying the default parameters. Daily discharge to the sewer is summarised in the table below. Emission to grassland and arable land are presented in the appendixes.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
emission to the STP		
Dairy cattle	no emission	
Beef cattle	no emission	
Pig farming	no emission	
Poultry	4.18E-02 kg iodine-iodide/d 5.69E-02 kg iodate/d	

PT4 – metaSPC 7, 8 and 9.

Disinfection of surfaces in the food industry

Scenario 1 describes the disinfection of surfaces in food industry with products of meta SPC 7 and 8. Working solution for both meta-SPC 7 and 8 contains 0.015% of iodine. The worst-case area to be disinfected is 2000 m² for large scale catering kitchens and canteens and 10 000 m² (for slaughterhouses) according to the ESD guidance for PT4. Iodine based products of meta SPC 7 and 8 are expected to be used daily. Results of assessment of meta-SPC 8 are therefore presented.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: surfaces disinfection			
Application rate of working solution	40	ml/m²	Worst-case value

Concentration of active substance in the working solution	0.032	% w/w	
Frequency of application per day	1	-	1 per day
Fraction of active released to waste water	1	-	
Fraction of substance eliminated due to on-site pre-treatment of waste water	0.2	-	As waste water from the food industry is usually purified before release to the municipal sewer, iodine will be partly removed by sorption onto lipids and grease in sedimentation tanks. The fraction was set equal to the fraction removed in a municipal STP.

Calculations for Scenario [1]

Emission to the STP was calculated according to the ESD by applying the default parameters. The results are summarised in the table below. Because waste water from professional kitchens, food industries, slaughterhouses, etc. is often purified prior to release to the sewer in order to fulfil the standards for e.g. lipids, solids, and biological oxygen demands, an additional refinement was added in which the fraction eliminated during emission (Felim) was set to 0.2. This value is equal to the fraction removed in the STP by adsoprtion.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission to the sewer after on-site treatment ($Elocal_{compartment}$)**	**Remarks**
large scale canteens	0.0205 kg iodine/d	20% reduction was assumed due to purification of waste water prior to release to the municipal sewer.
slaughterhouses	0.102 kg iodine/d	
total	0.123 kg iodine/d	

CIP disinfection in food industry

Scenario 2 describes the CIP disinfection in food industry with products of metaSPC 9. The Bakker scenario for Food, Drink and Milk industry is used (ESD guidance for PT4).

Results of assessment of metaSPC 9 are therefore presented.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: CIP disinfection in food industry			
Volume used to disinfect installations and process lines	274	L/d	A thin layer of working solution is expected to be on the wall of the tank. Most of pipes used in food industry are the ones with a length of 50 or 65 meter. In a pipe "DN 50" with 60.33 mm of diameter, the necessary amount needed is 2.86L of working solution per "m" of tube so 2.86x50=143L. In a pipe DN65, with a diameter of 73.03 mm, the necessary amount of working solution is 4.19x65=273.35L.
Volume used to disinfect mixing tanks	202	L/d	A thin layer of working solution is expected to be on the wall of the tank. The amount of product necessary is estimated to be equivalent to the internal surface of the tank. Capacity of mixing tanks is about 2000 to 10 000L. With a height of 3.2m and a diameter of 2m, the volume of working solution that is necessary for disinfection is 2x(2/2)*3.14*3.2*0 .01*1000=20.1L. A worst-case of 10

			tanks of 10 000L per facility is considered.
Volume used to disinfect storage tanks	522	L/d	A thin layer of working solution is expected to be on the wall of the tank. The amount of product necessary is estimated to be equivalent to the internal surface of the tank. Capacity of storage tanks is about 10000 to 60 000L. With a height of 10m and a diameter of 2.76m, the volume of working solution that is necessary for disinfection is 2x(2.76/2)*3.14*10 *0.01*1000=86.66L . An average of 6 tanks of 60 000L per facility is considered.
Concentration of active substance in the working solution	0.0125	g/L	/
Frequency of application per day	1	-	/

Calculations for Scenario [2]

Emission to the STP was calculated according to the ESD by applying the default parameters. The results are summarised in the table below.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$)**	**Remarks**
STP	0.0125 kg iodine/d	Scenario 2

CIP disinfection of milking parlours

Scenario 3 describes the CIP disinfection in milking parlour systems with products of metaSPC 9. The products are used twice a day after milking for disinfection of the milk

installation and the milk storage tank is expected to be disinfected once per day every 3 days. The worst-case is considered to be the day where both milk installation (x2/day) and storage tanks are disinfected. An emission scenario from Baumann is available in the ESD guidance for PT4 (pages 24-25).

Results of assessment of metaSPC 9 are therefore presented.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 3: CIP disinfection in milking parlours			
Volume used to disinfect milking installations	130	L/d	Working solution (ESD for PT4)
Volume used to disinfect milk storage tanks	45	L/d	Working solution (ESD for PT4)
Concentration of active substance in the working solution	0.0125	g/L	/
Frequency of application per day	1	-	ESD for PT4

Calculations for Scenario [3]

Emission to the STP was calculated according to the ESD for PT04. The results are summarised in the table below.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$)**	**Remarks**
STP	2.19E-03 kg iodine/d	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
PT3									
Scenario 1: teat disinfectants	Yes (1A & 1B)	Yes (A1 & 1B)	No	No	Yes (1B)	No	Yes (1A & 1B)	Yes (1A & 1B)	Secondary poisoning food chain

Scenario 2: animal housings	Yes (2A & 2B)	Yes (2A & 2B)	No	No	Yes (2B)	No	Yes (2A & 2B)	Yes (2A & 2B)	Secondary poisoning food chain
PT4									
Scenario 1: Surface disinfection in food industry	Yes	Yes	No	No	Yes	No	Yes	Yes	Secondary poisoning food chain
Scenario 2: CIP in food industry	Yes	Yes	No	No	Yes	No	Yes	Yes	Secondary poisoning food chain
Scenario 3: CIP in milking parlours	Yes)	Yes	No	No	Yes	No	Yes	Yes	Secondary poisoning food chain

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	253.81	g/mol	Source: ECHA[a], mol. weight for iodine (I_2)
Melting point	113.7	°C	Source: ECHA
Boiling point	184.5	°C	Source: ECHA
Vapour pressure (at 25°C)	1E-06	Pa	Source: ECHA Although iodide (I_2) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised iodine species are volatile. Therefore, emission to air was not considered.
Water solubility (at 25°C)	1E+05	mg/l	Source: ECHA. Value for the environmental relevant iodine species iodate and iodide. Solubility of iodine is 0.3 g/L.
Henry's law constant (12°C)	4.05E-07	Pa m³/mol	Calculated
Log Octanol/water partition coefficient	2.49	Log 10	inorganic substance

Organic carbon/water partition coefficient (Koc)	165.83	L/kg	not applied in the risk assessment. Overruled by Kp_{soil}.
Solids-water partition coefficient in soil (Kp_{soil})	5.8	L/kg	Source: ECHA
Solids-water partition coefficient in sediment (Kp_{sed})	200	L/kg	Source: ECHA
Solids-water partition coefficient in suspended matter (Kp_{susp})	220	L/kg	Source: ECHA
Biodegradability	Not biode-gradable		Inorganic substance[b]

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

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

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

Calculated fate and distribution in the STP (1B, 2B)		
Compartment	Percentage [%]	Remarks
	All scenarios	
Air	0	Source: ECHA[a], based on laboratory and field experiments
Water	80	
Sludge	20	
Degraded in STP	0	

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

Calculated PEC values

Disinfection of teats

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	2.07	2.07E-01	1.00E-02	--	1.00E-03	1.29E-02	2.46	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	1.93	9.39E-02	--	--	1.03E-01	19.4	--
arable land	--	1.18	5.73E-02	--	--	6.22E-02	11.8	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea\ water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	2.86	2.86E-01	1.38E-02	--	--	1.78E-02	3.4	--
via slurry/manure – concentrations after ten years. Leaching from the top soil layer between two applications is considered.								
grassland	--	2.67	1.30E-01	--	--	1.42E-01	26.81	--
arable land	--	1.63	7.92E-02	--	--	8.6E-02	16.31	--

Disinfection of animal housing

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea\text{-}water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
Dairy cattle	--	--	--	--	--	--	--	--
Beef cattle	--	--	--	--	--	--	--	--
Pig farming	--	--	--	--	--	--	--	--
Poultry	16.7	1.67	8.10E-02	--	--	0.104	0.02	--

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via slurry/manure – concentrations after ten years of successive manure applications on <u>grassland</u>. Leaching from the top soil layer between two applications is considered.								
Dairy cattle	--	6.70E-02	3.26E-03	--	--	3.52E-03	0.67	--
Beef cattle	--	8.82E-01	4.29E-02	--	--	4.63E-02	8.85	--
Pig farming	--	6.07E-01	2.95E-02	--	--	3.19E-02	6.09	--
Poultry, including duck farming	--	8.75E-01	4.25E-02	--	--	4.60E-02	8.78E+00	--
Poultry, excluding duck farming	--	3.256E-01	1.58E-02	--	--	1.71E-02	3.26E+00	--
via slurry/manure – concentrations after ten years of successive manure applications on <u>arable land</u>. Leaching from the top soil layer between two applications is considered.								
Dairy cattle	--	3.71E-02	1.80E-03	--	--	1.95E-03	0.37	--
Beef cattle	--	3.06E-01	1.49E-02	--	--	1.61E-02	3.07	--
Pig farming	--	2.65E-01	1.29E-02	--	--	1.39E-02	2.66	--
Poultry, including duck farming	--	5.27E-01	2.56E-02	--	--	2.77E-02	5.29E+00	--
Poultry, excluding duck farming	--	1.71E-01	8.33E-03	--	--	9.01E-03	1.72E+00	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
Dairy cattle	--	--	1.12E-01	--	--	--	--	--
Beef cattle	--	--	--	--	--	--	--	--
Pig farming	--	--	--	--	--	--	--	--
Poultry	23.1	2.30	0.112	--	--	0.144	0.03	--
via slurry/manure – concentrations after ten years of successive manure applications on grassland. Leaching from the top soil layer between two applications is considered.								
Dairy cattle	**--**	9.12E-02	4.43E-03	--	--	4.79E-03	0.92	--
Beef cattle	**--**	1.20E+00	5.84E-02	--	--	6.31E-02	12.0	--
Pig farming	**--**	8.25E-01	4.01E-02	**--**	**--**	4.34E-02	8.28	**--**
Poultry, including duck farming	**--**	1.19	5.79E-02	**--**	**--**	6.26E-02	11.9	**--**
Poultry, excluding duck farming	**--**	4.42E-01	2.15E-02	**--**	**--**	2.32E-02	4.44	**--**

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via slurry/manure – concentrations after ten years of successive manure applications on arable land. Leaching from the top soil layer between two applications is considered.								
Dairy cattle	--	5.05E-02	2.46E-03	--	--	2.65E-03	0.51	--
Beef cattle	--	4.16E-01	2.02E-02	--	--	2.18E-02	4.17	--
Pig farming	--	3.61E-01	1.75E-02	--	--	1.89E-02	3.62	--
Poultry, including duck farming	--	7.18E-01	3.49E-02	--	--	3.77E-02	7.20	--
Poultry, excluding duck farming	--	2.33E-01	1.13E-02	--	--	1.23E-02	2.34	--

Disinfection of surfaces in the food industry

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP without pre-treatment								
large scale canteens	10.2	1.02E+00	4.96E-02	--	--	6.36E-02	12.2	--
slaughter houses	51.0	5.10	2.48E-01	--	--	3.18E-01	60.4	--
total	61.3	6.12	2.98E-01	--	--	3.80E-01	72.6	--
via STP with pre-treatment								
large scale canteens	8.20	0.816	3.97E-02	--	--	5.09E-02	9.72	--
slaughter houses	40.8	4.07	1.98E-01	--	--	2.54E-01	48.3	--
total	49.0	4.90	2.38E-01	--	--	3.04E-01	58.0	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP without pre-treatment								
large scale canteens	14.17	1.41	6.86E-02	--	--	8.79E-02	16.8	--
slaughter houses	70.5	7.04	3.43E-01	--	--	4.37E-01	83.5	--
total	84.6	8.45	4.11E-01	--	--	5.25E-01	101	--
via STP with pre-treatment								
large scale canteens	11.33	1.13	5.48E-02	--	--	7.03E-02	13.43	--
slaughter houses	56.4	5.63	2.74E-01	--	--	3.50E-01	66.8	--
total	67.7	6.76	3.29E-01	--	--	4.20E-01	80.2	--

CIP disinfection in food industry

Summary table on calculated PEC values for iodine,iodide, and iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP without pre-treatment								
iodine/iodide	5.00	4.98E-01	2.42E-02	--	--	3.11E-02	5.94	--
iodate	6.91	6.89E-01	3.35E-02	--	--	4.29E-02	8.21	--

CIP disinfection of milking parlours

Summary table on calculated PEC values for iodine and iodide								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea-water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	0.875	8.72E-02	4.24E-03	--	--	5.44E-03	1.04	--

Summary table on calculated PEC values for iodate								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{sea\ water}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
via STP								
	1.21	0.121	5.86E-03	--	--	7.52E-03	1.43	--

Primary and secondary poisoning

Primary and secondary poisoning

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

C. RISK CHARACTERISATION

Atmosphere

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

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values - Iodine	
	PEC/PNEC$_{STP}$
Disinfection of teats (PT03)	
	<0.001
Disinfection of animal housing (PT03)	
Poultry	0.006
Disinfection of surfaces in the food industry (without pre-treatment of waste water, PT04)	
large scale canteens	0.004
slaughterhouses	0.018
total	0.021
CIP disinfection in food industry (PT04)	
	0.002
CIP disinfection of milking parlours (PT04)	
	<0.001

The ratio PEC/PNEC is inferior to 1 so the risk for STP is fully acceptable in first tier for all scenarios when residues are released to the sewer. Because all worst-case PEC:PNEC ratios are well below one, no additional risk mitigation measures are required to protect the municipal STP. However, (dairy) farms are not necessarily connected to the municipal sewer and domestic waste water may be purified on-site by individual sewage treatment plants. Considering that these systems are small (a few cubic meters), high loads of iodine may kill the microbial population therein instantly, resulting in malfunctioning of the installation. Therefore, a precautionary measure stating that residues must be discharged to the (liquid) manure depot or municipal sewer will be added to the SPC.

Aquatic compartment

As no PNEC values are available for sediment, the endpoints are usually derived using equilibrium partitioning. Because the same approach is applied for the PECs, the risk ratios

are consequently similar to those for surface water. Risk ratios are therefore not presented in the current risk assessment report, but only compared to the natural background concentrations.

Disinfection of teats

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	$PEC/PNEC_{water}$					
via STP						
	iodine		iodide		iodate	
Dairy cattle	0.35		0.249		<0.005	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	Grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	**3.27**	**2.33**	0.046	**2.00**	**1.42**	0.028

For the emission pathway via STP, the PEC/PNEC values for iodine, iodide and iodate in the aquatic compartment (surface water incl. sediment, marine water incl. sediment) are below the trigger value of 1 (max. 0.35). Therefore, unacceptable risk for the aquatic environment cannot be expected.

Although iodate is the dominant iodine specie in soils under aerobic conditions, it may be transformed to iodide once entering the aquatic environment depending on the acidity and redox potential (oxygen concentrations). The maximum PEC/PNEC value for iodide is 2.33 after ten years of successive manure applications, while iodate results in a PEC:PNEC ratio of 0.046. Unacceptable risks may be expected in surface water low in oxygen. Iodine is however a natural occurring compound for which aquatic background levels are reported between 0.5 and 20 µg/L. Moreover, many uncertainties exist as currently available higher tier modelling (FOCUS PEARL, SWASH) are not suitable for inorganic substances such as iodine. It was therefore agreed that the natural background concentration replaces the PNEC as environmental standard. The accompanied risks are therefore considered acceptable.

Disinfection of animal housing

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	PEC/PNEC$_{water}$					
via STP						
	iodine		iodide		iodate	
Poultry	**2.82**		**2.01**		0.039	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	0.114	0.079	0.002	0.063	0.044	<0.001
Beef cattle	**1.50**	**1.05**	0.021	0.518	0.363	0.007
Pig farming	**1.03**	0.720	0.014	0.449	0.314	0.006
Poultry (with ducks)	**1.48**	**1.04**	0.020	0.894	0.6262	0.012
Poultry (without ducks)	0.551	0.386	0.008	0.291	0.203	0.004

Release to the STP may result in unacceptable risks for the aquatic environment as the PNECs are exceeded when iodine is transformed into iodide, but risks are acceptable for oxygen-rich water as iodine is transformed in iodate that is less toxic towards aquatic organisms. Although the risks are exceeded, the accompanied risks are considered acceptable as release from stable is intermittent, i.e. 1-7 times per year, except from duck farming that is disinfected 13 times annually.

Runoff and drainage from agricultural land may result in a slight exceeding of the risks in adjacent surface water. Considering that the expected concentrations are well within the natural background , the accompanied risks are considered acceptable.

Disinfection of surfaces in the food industry

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	PEC/PNEC$_{water}$		
via STP			
	iodine	iodide	iodate
	without pre-treatment		
large scale canteens	**1.73**	**1.23**	0.024
slaughterhouses	**8.63**	**6.1**	0.121
total	**10.4**	**7.4**	0.145

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	PEC/PNEC$_{water}$		
	with pre-treatment		
large scale canteens	**1.38**	0.984	0.019
slaughterhouses	**6.90**	**4.91**	0.096
total	**8.3**	**5.9**	0.116

Application of iodine-based disinfectants results in unacceptable risks for surface water in case iodine is transformed into iodide, i.e. in water that is low of oxygen. The highest risks are expected for slaughterhouses being a represent for application in food, feed, and beverage industries (large scale application), but application in professional kitchens and canteens may result in an exceedance of the PNEC as well even when waste water is released to the sewer unpurified. The maximum expected concentration (6.12 µg/L) is however within the natural background concentration (0.5-20 µg/L). Moreover, Dutch surface water to which sewage effluents are discharged are generally close to oxygen saturation[3] and therefore the least toxic iodine specie iodate will be predominant[4]. No unacceptable risks are therefore expected and no risk mitigation measure are deemed necessary.

CIP disinfection in food industry

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	PEC/PNEC$_{water}$		
via STP			
	iodine	iodide	iodate
	0.844	0.559	0.012

No unacceptable risks are expected when iodine is applied as a CIP disinfectant in the food industry. This intended use is therefore considered acceptable without risk mitigation measures.

CIP disinfection of milking parlours

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

[3] 30 jaar Rijnwater. Deel 1 – Algemene parameters. Monitoring report published by RIWA, Nieuwegein, The Netherlands, March 2009 (in Dutch and German).

[4] Morgenstern, P.P., J.D. te Biesebeek, L. Breebaart, R. Ritseman, and J.F.M. Versteegh. Resultaten meetprogramma drinkwater 2000: Jodide en Jodaat. RIVM report 703713015/2001, Bilthoven, The Neterlands, 2001. In Dutch with English summary.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	PEC/PNEC$_{water}$		
via STP			
	iodine	iodide	iodate
Dairy cattle	0.148	0.105	0.001

No risks are expected when residues are released to the sewer. Therefore, iodine is applicable safely and no risk mitigation measures are necessary.

Sediment

The highest PEC (2.98E-01 mg/kg wwt) is well below the natural background concentration of 6 mg/kg. Therefore, emission of iodine does not result in an unacceptable increase of the natural background.

Terrestrial compartment

Disinfection of teats

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	PEC/PNEC$_{soil}$					
via STP						
	iodine		iodide		iodate	
Dairy cattle	**1.09**		**2.99**		0.059	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	Grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	**8.74**	**24.0**	0.469	**5.26**	**14.4**	0.282

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

Iodine and iodine species occur naturally in the terrestrial environment for which natural global mean background concentration is 5 mg/kg dwt and varies with geographical locations and local geology. The background concentrations in sandy and clayey soils varies between 1.7-5.4 and 2.1-8.9 mg/kg dwt, respectively, while peaty soils may contain 18.7-98.2 mg/kg dwt. The expected PECs after ten years (0.103 mg iodine/kg wwt in grassland and 0.0622 mg iodine/kg wwt in arable land) are in the lower range and therefore a significant increase of the background concentration cannot be expected. However, one should realise that atmospheric deposition is double as anthropogenic imission to soils due to teat disinfection is 31.7 g/ha/y5 and natural atmospheric deposition 25.6 g/ha/y6. However, the accompanied risks are nevertheless acceptable as the PEC:PNEC ratios for the dominant iodine specie in soils (iodate) remains below one. Despite an increase of background concentrations unacceptable risks in soils are not expected.

Disinfection of animal housing

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products						
	$PEC/PNEC_{soil}$					
via STP						
	iodine		iodide		iodate	
Poultry	**8.80**		**24.2**		0.472	
via slurry/manure – PEC:PNEC ratios after ten years. Leaching from the top soil layer between two applications is considered.						
	grassland			arable land		
	iodine	iodide	iodate	iodine	iodide	iodate
Dairy cattle	0.298	0.806	0.016	0.165	0.447	0.009
Beef cattle	**3.93**	**10.6**	0.207	**1.36**	**3.68**	0.072
Pig farming	**2.70**	**7.30**	0.143	**1.18**	**3.19**	0.062
Poultry (with ducks)	**1.45**	**10.5**	0.106	**2.35**	**6.34**	0.124
Poultry (without ducks)	0.763**1.18**	**3.91**	0.076	0.763	**2.06**	0.040

5 1.34 kg iodine is release to the manure intended for grassland or arable land (ESD outcome). Cows produce 7185 kg nitrogen annually (ESD default) which requires 42.3 ha agricultural land considering a nitrogen emission standards of 170 kg/ha for both arable land and grassland.

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

As explained previously, the risks for the soil compartment are considered acceptable assuming that iodate it the dominant iodine specie in agricultural soils. No risk mitigation are necessary.

Disinfection of surfaces in the food industry

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	$PEC/PNEC_{soil}$		
via STP			
	iodine	iodide	iodate
	without pre-treatment		
large scale canteens	**5.39**	**14.8**	0.289
slaughterhouses	**27.0**	**74.0**	**1.45**
total	**32.4**	**88.8**	**1.74**
	with pre-treatment		
large scale canteens	**4.31**	**11.8**	0.231
slaughterhouses	**21.6**	**59.2**	**1.16**
total	**25.9**	**71.0**	**1.39**

Distribution of sewage sludge results in unacceptable risks for the terrestrial environment. Although the highest risks are calculated for iodide, this iodine specie is uncommon in aerobic agricultural soils as explained previously. Nevertheless, the expected concentrations (0.051-0.253 mg/kg dwt) are in the lower range of the background concentration and therefore an significant increase of the background concentration cannot be expected. Because values of PEC/PNEC for iodate is below one for both large scale canteens and slaughterhouses , no risks can be expected.

CIP disinfection in food industry

The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	$PEC/PNEC_{soil}$		
via STP			
	iodine	iodide	iodate
	2.63	**7.23**	0.141

Assuming that iodine is transformed into iodate in agricultural soils as explained previously, no risks can be expected as the PEC is below the PNEC.

CIP disinfection of milking parlours
The risk evaluation (PEC:PNEC ratios) for the aquatic compartment when residues are released to the STP or due to runoff from fertilised agricultural land is presented below.

Summary table on calculated PEC/PNEC values for iodine and their transformation products			
	$PEC/PNEC_{soil}$		
via STP			
	iodine	iodide	iodate
Dairy cattle	0.461	**1.26**	0.018

Assuming that iodine is transformed into iodate in agricultural soils, no risks can be expected as the PEC is below the PNEC as explained previously. No risk mitigation measures are deemed necessary.

Groundwater

The concentrations in groundwater for the different intended uses are summarised below.

Concentrations in pore water (µg/L)				
	via STP		via slurry/manure	
	iodine/iodide	Iodate	iodine/iodide	iodate
Disinfection of teats				
	2.46	3.4	11.8-19.4	16.3-26.8
Disinfection of animal housing				
Dairy cattle	<0.001	3.01E-04	0.67	0.93
Beef cattle	<0.001	1.64E-04	8.86	12.25
Pig farming	<0.001	2.57E-04	6.09	8.42
Poultry	<0.001	1.51E-03	5.25	7.26
Poultry. excluding duck farming	-	-	2.66	3.67
Disinfection of surfaces in the food industry				
large scale canteens	9.72-12.15	13.43-16.8	-	-
slaughterhouses	48.33-60.41	66.8-83.48	-	-
total	58.05-72.56	80.22-100.3	-	-

Concentrations in pore water (µg/L)				
CIP disinfection in food industry				
	5.94	8.21	-	-
CIP disinfection of milking parlours				
	1.04	1.437	4.10-6.72	5.66-9.29

Concentrations in groundwater are expected to exceed the threshold limit value of 0.1 µg/L for the majority of the intended uses. It should be however noted that the 0.1 µg/L limit is set for organic chemicals and therefore not feasible for iodine. Therefore, the predicted concentrations were compared to natural background concentrations.
Iodine is a natural occurring compound occurring in groundwater for which the concentration ranges from 1 to 70 µg/L (the latter are found in coastal and arid areas). Anthropogenic emission may therefore increase the natural background concentrations up to 72.9 in case groundwater is low in iodine, but the expected concentrations are still below the highest background concentration (70 µg/L). As the concentrations are in line with dose presented in the CAR, the expected exceeding is considered acceptable.

Primary and secondary poisoning

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

Mixture toxicity

Mixture toxicity is not relevant, risk assessments on iodine, iodine species and SoCs are considered to represent a worst-case.

Aggregated exposure (combined for relevant emmission sources)

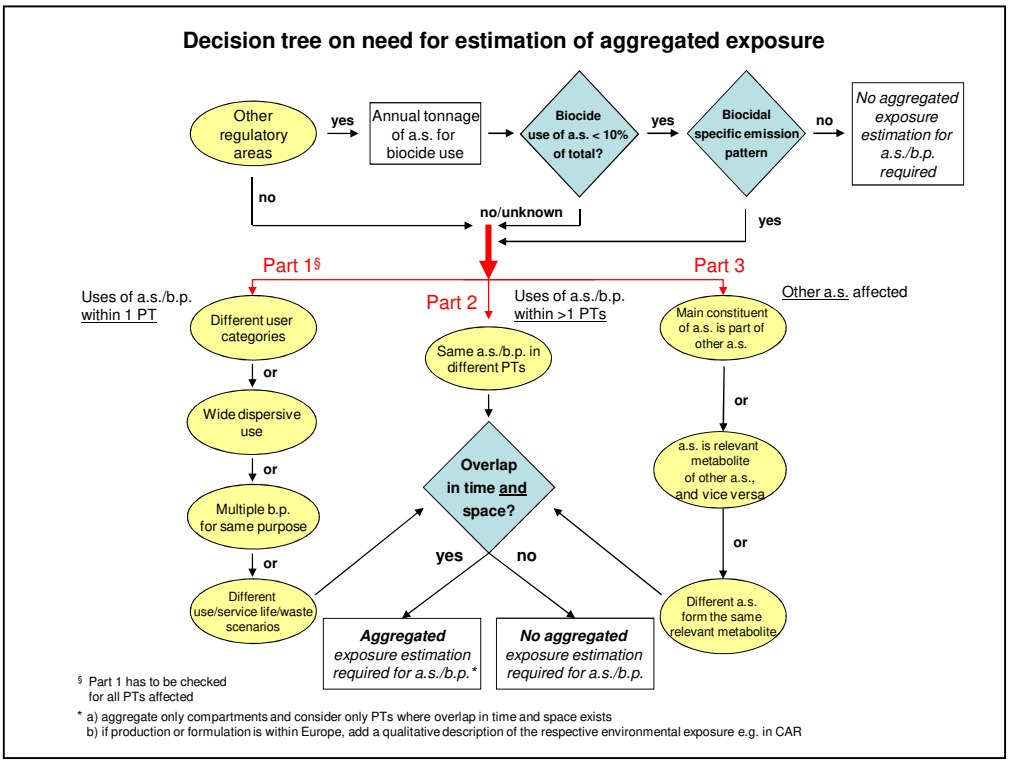


Figure 1: Decision tree on the need for estimation of aggregated exposure

An aggregated risk assessment is necessary for PT3 and PT4 uses that can end up in the same STP. Exposures via STP following teat disinfection (PT3), surface disinfection in food industry (PT4) and CIP disinfection in food industry and in milking parlours (PT4) are taken in account. Exposures following skin disinfection and stables disinfection (PT3) are not considered because use is expected to be occasional.

	Summary table on total PEC/PNEC values for iodine and their transformation products		
	Iodine	Iodide	Iodate
STP	<0.02	-	-
Surface water	**5.8**	**4.1**	0.08
Soil	**18.04**	**49.5**	0.97

Conclusion:

Values of PEC/PNECs are below 1 for STP so the risk is acceptable. For surface water ratio is above 1 for iodine and iodide. Nevertheless, maximum exposure is 3.3 µg/L of Iodine which corresponds to the lower end of the aquatic background levels between 0.5 and 20 µg/L. Ratio for iodate in surface water is below 1. The slight exceedance of the PNEC is mainly due to the use in food industry and is comparable to the CAR therefore risk is considered as acceptable. In soil, ratios are also above 1 for iodine and iodide. Nevertheless maximum exposure is 0.2 mg/kg wwt for iodine which corresponds to the lower range of natural background concentrations (1.7 mg/kg dwt in sandy soil to 98.2 mg/kg dwt in peaty soil with a mean background of 5 mg/kg dwt). However iodiate is the

dominant specie in soil and ratio for iodate are below 1 so the risk is acceptable. In groundwater the ratio is already above 1 for each of the uses considered in the aggregated assessment. Therefore the risk is also above 1 in the aggregated assessment. Nevertheless maximum aggregated exposure is about 40 µg/L which is still within the natural background concentrations of 1 to 70 µg/L. As the concentrations are in line with the ones presented in the CAR, risk is considered as acceptable.

Measures to protect man, animals and the environment

[Please include relevant information and considerations on each of the following.]

MetaSPC's 1, 10 and 7:
After eye contact: Rinse immediately with plenty of water for 15 minutes. Obtain emergency medical attention if pain, blinking, tears or redness persist.
After ingestion: Rinse mouth. Spit. Do NOT induce vomitting. Seek medical attention immediately

MetaSPC's 8 and 9:
After inhalation: Remove victim to fresh air. Allow the victim to rest. Obtain medical attention if breathing difficulty persists.
After skin contact: Remove contaminated clothing and shoes. Flush with plenty of water. Seek medical attention if ill effect or irritation develops.
After eye contact: Rinse immediately with plenty of water.
After ingestion: Rinse mouth. Do NOT induce vomitting. If swallowed, seek medical advice immediately and show the container or label.

MetaSPC's 2, 3, 4, 5 and 6, 12:
After eye contact: Rinse immediately with water.
After ingestion: Rinse mouth. Spit.

A. RECOMMENDED METHODS AND PRECAUTIONS

Keep only in the original container in a cool, well ventilated place. Keep container closed when not in use.
Protect from frost. Do not expose to temperatures >40°C.
The shelf-life of the products in metaSPCs 1, 2, 3, 4, 6, 7, 8, 9, 10, 11 and 12 is 2 years.
The shelf-life of the products in metaSPC 5 is 18 months.

Dilutions of products can be stored for 1 week in which they remain stable.

In case of fire: all extinguishing media can be used.

B. IDENTITY OF RELEVANT COMBUSTION PRODUCTS IN CASES OF FIRE

When heated and in case of fire, corrosive vapours/gases may be formed.

C. SPECIFIC TREATMENT IN CASE OF AN ACCIDENT

[e.g. first- aid measures, antidotes, medical treatment if available; emergency measures to protect the environment]

Spill should be handled by trained cleaning personnel properly equipped with respiratory, skin and eye protection.
Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public water.

D. POSSIBILITY OF DESTRUCTION OR DECONTAMINATION FOLLOWING RELEASE

[Please indicate here possibility of destruction or decontamination following release in or on the following: air; water, including drinking water; soil]

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

[Please indicate here procedures for waste management of the biocidal product and its packaging for industrial use, use by trained professionals, professional users and non- professional users (e.g. possibility of reuse or recycling, neutralisation, conditions for controlled discharge, and incineration)]
The packing and content must be eliminated as dangerous waste product under the whole responsibility of the possessor of this waste product. Do not throw wastes into sewers and watercourses. Dispose in a safe manner in accordance with local/national regulations.

F. PROCEDURES FOR CLEANING APPLICATION EQUIPMENT WHERE RELEVANT

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

[Please specify here any repellents or poison control measures included in the product that are present to prevent action against non-target organisms]

Assessment of a combination of biocidal products

Cumulative exposures of workers to iodine or SoCs following concomitant uses of products of the BPF do not show any unacceptable risk considering that workers are advised to wear gloves when disinfecting the teats by spraying, when disinfecting surfaces of animal housings and when manipulating pure products (for dilution, pumping, pouring steps).

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products]

Comparative assessment

Not relevant

ANNEXES

1. LIST OF STUDIES FOR THE BIOCIDAL PRODUCT FAMILY:

- Stability reports are presented in part 3.4.1 of the IUCLID file.
- GLP testing reports are presented (iodine determination, viscosity, alkalinity, density) in part 5 of the IUCLID file.
- Efficacy reports are presented in part 6.7 of the IUCLID file.
- Foaming testing reports are presented in part 3.5 of the IUCLID file.

List of new data submitted in support of the evaluation of the active substance

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
Human health assessment	Not precised	[redacted]	2013	Iodine concentrations in milk	[redacted]	x	
Human health assessment	BC124-00002	SCC	2015	Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety	SCC Scientific Consulting Company	x	

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

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted Yes	No
Human health assessment Environmental assessment Labels and instructions for use	Not precised	[redacted]	2017	Test report: Consumption test of Iodine spraying & dipping products, [redacted], CIRLAM, 04/08/2017.	CIRLAM	x	
Human health assessment				Discussion paper – iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety	IRG	x	

BPR datapoint	Study No	Author	Year	Title	Owner of data	Confidentiality request submitted	
Human health assessment	Not precised	[redacted]	2017	Residue report: Determination of iodine content after application of Metas SPC 8 on inox.	CIRLAM	x	
Environmental assessment	55SPC1.2052015	Cirlam	2017	Environmental risk assessment v2 PT3 teat disinfectants	CIRLAM	x	
Environmental assessment	63SPC1.9062015	Cirlam	2017	Environmental risk assessment v2 PT4 CIP disinfectants	CIRLAM	x	

2. OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

Risk assessment reports for human exposure (including residues in food exposure) are presented in part 8 of the IUCLID file.
Output tables are included in the confidential annex of the PAR.
Risk assessment reports for livestock exposure are presented in part 8 of the IUCLID file.
Risk assessment reports for environmental exposure are presented in part 9 of the IUCLID file.

Highlights Risk assessment reports for human exposure please see confidential annex section 6.

3. NEW INFORMATION ON THE ACTIVE SUBSTANCE

Not relevant All information on the active substance are from the CAR on Iodine. No further investigation was performed.

4. RESIDUE BEHAVIOUR

Residues in food are presented in the IRG study report and estimated in the risk assessment reports for human exposure (part 8 of the iuclid file).
Residues in environmental comaprtments are not necessary according to the CAR on iodine. No further investigation was performed.

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

Efficacy reports are presented in part 6.7 of the IUCLID file.

6. CONFIDENTIAL ANNEX

See separate document

7. OTHER

Information on the mode of use

Disinfection of skin is expected to be occasional because the aim is only to avoid cross contamination in the farmhouses therefore the products will be applied on trigger animals only and within specific conditions. It concerns then new animal joining the herd (dairy cow, beef cattle) and disinfection of udder of sows before and after farrowing. The details on modes of use are described in the following table:

Target species	Mode of use #	Mode of use
Dairy cattle and beef cattle	M1	Product is used on skin of udder before calving once a day: 2 days before calving and 2 days after. Product is applied by spraying (1spray per udder). Cows give birth 1 per year.
Sows in group or individual	M3	Product is applied on the udder of the sows before farrowing to avoid cross contamination (50 mL of

		product per animal), once a day, 1 day before farrowing and 4 days after.

It appears clearly that the use of products included in metaSPC 3, 4 and 6 for skin is expected to be **occasional** because responding to a specific claim of avoid cross contamination.

Therefore we believe that exposure to the products included in metaSPC 3, 4 and 6 for this specific use is fully covered by exposure following products included in metaSPC 1, 2, 5, 10, 11, 12 (teat disinfection use expected to regular) or following products included in metaSPC 7 and 8 (animal housings disinfection with higher exposure of the environment). In conclusion the uses of products included in metaSPC 3, 4 and 6 for skin disinfection are not expected to contribute significantly to the aggregated exposure assessment.

Dipping bath for hooves is not assessed because this is not claimed on label.
Footbath disinfectants are usually not based on iodine, but on copper sulphate or formaldehyde.
This is coherent with the market research conducted by CID LINES sales managers. CID LINES is also member of IRG group. Assessments proposed by IRG and included in the CAR does not cover footbath routine use because none of the applicants wanted it.

A study[1] has been done at CIRLAM Laboratory on the teat disinfectants Kenodin SD 400 (SPC 1.1.2), Kenodin SD 900 (SPC 1.1.1), Kenodin SD (SPC 1.4.1), Kenodin SD 5000 (SPC 1.2.4) and Iodo SD PVP (SPC 1.5.2) to measure the consumption of spray products for 1 treatment.
The results for consumption of Kenodin SD 400, Kenodin SD 900, Kenodin SD, Kenodin SD 5000 and Iodo SD PVP are that an approximate value of 1.2 mL of working solution delivered by 1 spraying is found.
The above mentioned study [1] is included in section 8 "Toxicological profile for humans and animals" of the IUCLID file.

The above mentioned study [1] is included in section 8 "Toxicological profile for humans and animals" of the IUCLID file.

[1] Test report: Consumption test of Iodine spraying & dipping products, [redacted], CIRLAM, 04/08/2017.

Additional information on skin disinfection (udder):

The mode of use M1: dairy cows: Product is used on skin of udder before calving once a day: 2 days before calving and 2 days after. Product is applied by spraying (1spray per udder). Cows give birth 1 per year. It means 4 sprays per cow (1 per teat) 1.2 mL*4=4.8 mL per cow, 1/day, 4 days per cow, max 30% of the herd.

The mode of use M3: sows: Product is applied on the udder of the sows before farrowing to avoid cross contamination (20 mL of product per animal), once a day, 1 day before farrowing and 4 days after.

A study[1] has been done at CIRLAM Laboratory on the teat disinfectants Kenodin SD 400 (SPC 1.1.1), Kenodin SD 900 (SPC 1.10.1), Kenodin SD (SPC 1.4.1), Kenodin SD 5000 (SPC 1.2.4) and Iodo SD PVP (SPC 1.5.2) to measure the consumption of spray products for 1 treatment.
The results for consumption of Kenodin SD 400, Kenodin SD 900, Kenodin SD, Kenodin SD 5000 and Iodo SD PVP are that maximum 5 mL of working solution is needed per cow to disinfect half of the length of the teats for both kind of application.
Also an approximate value of 1.2 mL of working solution delivered by 1 spraying is found.
The above mentioned study [1] is included in section 8 "Toxicological profile for humans and animals" of the IUCLID file.

[1] Test report: Consumption test of Iodine spraying & dipping products, [redacted], CIRLAM, 04/08/2017.

Note on dosages for surface disinfection:

We believe that 40 mL/m2 are sufficient as a thin film is efficient for both PT3 and PT4. A report[1] describes that most factories in food industry work with an application rage of less than 40 mL m^{-2}.

Therefor we propose to set both dosages for PT3 and PT4 at 40 mL per m2 as dosage for surface disinfection.

We will add the following sentence in SPC for metaSPC 7 and 8 "Do not prepare more fluid than necessary. Make 0.04 L solution for every square meter that has to be disinfected."

[1] Biocide use in the food industry and the disinfectant resistance of persistent strains of *Listeria monocytogenes* and *Escherichia coli*, J.T. Holah, J.H. Taylor, D.J. Dawson and K.E. Hall, 2002

NO FURTHER INVESTIGATION WAS PERFORMED.