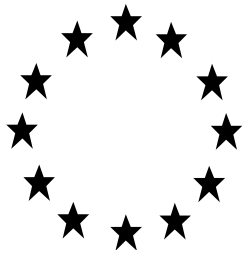
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the UK Competent Authority)



Deosan Activate BPF based on Iodine

PT3

Iodine

Case Number in R4BP: BC-JN018376-30

Evaluating Competent Authority: UK CA

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1 CONCLUSION

The outcome of the assessment for Deosan Activate BPF based on Iodine is specified in the BPC opinion following discussions at the BPC-26 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

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

1.1.1 Usage area

User	Application method	Product type
Professional	Applied directly to animal teats pre and/or post milking as follows; **SOLUBLE CONCENTRATE & RTU LIQUID:** **Pre and/or post milking** Manual dipping, manual foaming and manual spraying**.** **Post milking** Automatic spraying and semi-automatic dipping **RTU GEL** **Pre and/or post milking** Manual dipping **Post milking** Semi-automatic dipping	PT3- Veterinary hygiene (disinfectant)

1.1.2 Authorised uses

Authorisation is granted for professional, indoor use, for direct application to animal teats (e.g. cows or other milkable animals) to kill bacteria and yeast. The products may be applied pre milking only, post milking only or pre and post milking, depending on the formulation type and application methods, as stated in section 1.1.3

1.1.3 Application rates and frequency

Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For effective use against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds.

	For concentrated product; dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. Ready-to-use liquid and gel formulations contain 0.3% (w/w) Iodine. These products should not be diluted before use. **SOLUBLE CONCENTRATE** 3 pre milking and/or 3 post milking applications, per animal, per day (for manual dipping, manual foaming and manual spraying) 5 post milking applications, per animal, per day (for post milking automatic spraying. Not to be combined with iodine based pre-milking disinfection. 3 post milking applications per day (for post milking, semi-automatic dipping) **RTU LIQUID** 3 pre milking and/or 3 post milking applications, per animal, per day (for manual dipping, manual foaming and manual spraying) 5 post milking applications, per animal, per day (for post milking automatic spraying. Not to be combined with iodine based pre-milking disinfection. 3 post milking applications per day (for post milking, semi-automatic dipping) **RTU GEL** 3 pre milking and/or 3 post milking applications, per animal, per day (for manual dipping) 3 post milking applications per animal, per day (for post milking, semi-automatic dipping) **Maximum quantity of product per application;** **Dipping:** apply a maximum of 10 ml product/animal/application **Foaming**: apply a maximum of 5 ml product/animal/ application **Spraying**: apply a maximum of 15 ml product/ animal /application

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

The concentration of the active substance Iodine in the biocidal product family is 0.30 - 1.60% w/w. The sources of the formulated active substances are:

ACF Minera S.A.

Sociedad Quimica y Minera (SQM) S.A.

Cosayach Nitratos S.A.

Nihon Tennen Gas Development Co., Ltd.

ISE Chemicals Corporation

Atacama Minerals SCM

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

1.2 Necessary issues accounted for in the product label

Meta SPC 1 - Deosan Activate BPF – concentrate

- Use# 3 and use# 6 only: Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).
- Use# 11 only: Wear protective chemical resistant gloves, boots and clothing (coated coveralls) when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).
- For effective use against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds.
- For pre milking application: after the appropriate contact time, thoroughly remove the product, using a single service paper towel/cloth to ensure teats are clean and dry.
- For pre-milking application: 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/post-milking disinfection
- For post milking application: To ensure sufficient contact time for post-milking application, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
- For post milking application: 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/post-milking disinfection
- Protect from frost
- Do not store at temperatures above 40^{o}C

Meta SPC 2 - Deosan Activate BPF – RTU liquid;

- Use# 14, 17, 20 & 21 only: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- Use# 22 only: Wear protective chemical resistant gloves, boots and clothing (coated coveralls) when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).
- For effective use against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds.

- For pre milking application: after the appropriate contact time, thoroughly remove the product, using a single service paper towel/cloth to ensure teats are clean and dry.

- For pre-milking application: 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/post-milking disinfection

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

- For post milking application: 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/post-milking disinfection

- Protect from frost

- Do not store at temperatures above 30°C

Meta SPC 3 - Deosan Activate BPF – RTU gel;

- Use# 26 only: Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

- For effective use against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds.

- For pre milking application: after the appropriate contact time, thoroughly remove the product, using a single service paper towel/cloth to ensure teats are clean and dry.

- For pre-milking application: 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/post-milking disinfection

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

- For post milking application: 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/post-milking disinfection

- Protect from frost

- Do not store at temperatures above 30°C

1.3 Requirement for further information

None.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[1]	**Country (if relevant)**
Deosan Activate BPF based on Iodine	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Diversey Europe Operations B.V.
	Address	Maarssenbroeksedijk 2 3542DN Utrecht Netherlands
Pre-submission phase started on	4th January 2015	
Pre-submission phase concluded on	16th March 2015	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands
Location of manufacturing site 1	Strada Statale 235 I – 26010 Bagnolo Cremasco (CR) Italy
Location of manufacturing site 2	Avenida Conde Duque 5 7 y 9 Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain
Location of manufacturing site 3	Rembrandtlaan 414 7545 ZW Enschede Netherlands
Location of manufacturing	Cotes Park Industrial Estate

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

site 4	DE55 4PA Somercotes Alfreton United Kingdom
Location of manufacturing site 5	Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

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

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

Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Address of manufacturer	Los Militares 4290 Piso 4, Las Condes Santiago Chile
Location of manufacturing sites	Nueva Victoria plant Pedro de Valdivia plant Northern Chile
[redacted]	[redacted]

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Hnos Amunátegui 178 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala Pozo Almonte Chile
[redacted]	[redacted]

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd.
Address of manufacturer	See below.
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun, Chiba 299-4205, Japan.
[redacted]	[redacted]

	[redacted]

Active substance	Iodine
Name of manufacturer	ISE Chemicals Corporation
Address of manufacturer	3-1, Kyobashi 1-Chome, Chuo-ku, Tokyo
Location of manufacturing sites	Shirasto Plant (3695 Kitaimaizumi, Oamishirasato City, Chiba, Japan.
[redacted]	[redacted]

Active substance	Iodine
Name of manufacturer	Atacama Minerals SCM
Address of manufacturer	Coronel Pereira No 72 Of. 701, Las Condes, Santiago, Chile
Location of manufacturing sites	Atacama Minerals SCM, Aguas Blancas Facility, Antofagasta, Chile.
[redacted]	[redacted]

2.1.2 Product (family) composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

Iodine is not a Candidate for Substitution as it does not meet the criteria stated in Article 10 of Regulation (EU) 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 258/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine†	Iodine	Active substance	7553-56-2	231-442-4	0.3	1.6

† In the CAR of Iodine it is stated that Iodine is usually stabilised in 2 ways using Iodophor Type 1 or Iodophor Type 2. The products in the Deosan Activate BPF based on Iodine contain both Iodophor Type 1 and Iodophor Type 2.

The full product family formulation composition details are contained within the Confidential Annex of this PAR (section 3.4.1).

Tolerance limits are ± 15 % of the nominal iodine content for each biocidal product within the BPF, and therefore each meta-SPC and the BPF as a whole.

2.1.2.4 Information on technical equivalence

Three of the notified sources of iodine (ACF Minera S.A., Sociedad Quimica y Minera (SQM) S.A. and Cosayach Nitratos S.A.) are the same as those considered for inclusion in the Union list of approved active substances. [redacted]

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex.

2.1.2.6 Type of formulation

Soluble concentrate (SL):	Deosan Activate BPF meta level concentrate
Any other liquid (AL):	Deosan Activate BPF meta level RTU liquid
Water soluble gel (GW):	Deosan Activate BPF meta level RTU gel

2 Please delete as appropriate.

2.1.3 Hazard and precautionary statements[3]

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

Classification	
Hazard category	Meta-SPCs 1-3: Aquatic chronic, category 3
Hazard statement	Meta-SPCs 1-3: H412, Harmful to aquatic life with long lasting effects
Labelling	
Signal words	No signal word.
Hazard statements	Meta-SPCs 1-3: H412, Harmful to aquatic life with long lasting effects
Precautionary statements	Meta-SPCs 1-3: P101 – If medical advice is needed, have product container or label at hand. P102 – Keep out of reach of children. P273 – Avoid release to the environment. P501 – Dispose of contents and containers in accordance with national regulation.
Note	**-**

2.1.4 Authorised use(s)

2.1.4.1 Use description[4]

Meta SPC 1 - Deosan Activate BPF – concentrate

Table 1. Use # 1 – Pre-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual dipping method.

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

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

	Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking applications, per animal, per day. Apply a maximum of 10 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 2. Use # 2 – Pre-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual foaming method. Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

	3 pre milking applications, per animal, per day. Apply a maximum of 5 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 3. Use # 3 – Pre-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual spraying method. Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking applications, per animal, per day. Apply a maximum of 15 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 4. Use # 4 – Post-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of	Teat disinfectant, for direct application to lactating animals post-milking

the authorised use	
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual dipping method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 5. Use # 5 – Post-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual foaming method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and	In use Iodine concentration of 3000mg/Kg (0.3% w/w)

frequency	For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 6. Use # 6 – Post-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual spraying method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 7. Use # 7 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via automatic spraying method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 8. Use # 8 – Post-milking disinfection, Semi-automatic dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor

Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 9. Use # 9 Pre and post-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual dipping method. For pre milking: Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Applied directly to animal teats post milking via manual dipping method.

	Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 10 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 10. Use # 10 Pre and post-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post-milking via manual foaming method. For pre-milking: Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)

Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 5 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 11. Use # 11 Pre and post-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual spraying method. For Pre-Milking: Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

	3 pre milking and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 15 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Meta SPC 2 - Deosan Activate BPF – RTU liquid

Table 12. Use # 12 Pre-milking disinfection, Manual dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual dipping methods. Pre-milking Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional

Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 13. Use # 13 – Pre-milking disinfection, Manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual foaming method. Pre-milking Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 14. Use # 14 Pre-milking disinfection, Manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an	Teat disinfectant, for direct application to lactating animals

exact description of the authorised use	pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual spraying method. Pre-milking Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 15. Use # 15 – Post-milking disinfection, Manual dipping (RTU liquid)

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

	Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 16. Use # 16 – Post-milking disinfection, Manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual foaming method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day.

	Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 17. Use # 17 – Post-milking disinfection, Manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual spraying method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 18. Use # 18 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via automatic spraying method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 29. Use # 19 – Post-milking disinfection, Semi-automatic dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor

Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 20. Use # 20 – Pre and post milking disinfection, manual dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual dipping methods. For pre-milking: Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking.

	To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 21. Use # 21 – Pre and post milking disinfection, manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual foaming method. For pre-milking: Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w)

	Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking and 3 post-milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 22. Use # 22 – Pre and post milking disinfection, manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual spraying method. For pre-milking Apply product to full length of each teat. For use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total)

	Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Meta SPC 3 - Deosan Activate BPF – RTU gel

Table 23. Use # 23 – Pre-milking disinfection, Manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre- milking via manual dipping application method. Pre-milking Apply product to full length of each teat. For effective use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre milking applications, per cow, per day. Apply a maximum of 10 ml product/cow/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 24. Use # 24 – Post-milking disinfection, Manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual dipping application methods. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 25. Use # 25 – Post-milking disinfection, Semi-automatic dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	Bacteria Yeast

Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping application method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 26. Use # 26 – Pre and post-milking disinfection, manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual dipping application method. For pre-milking Apply product to full length of each teat. For effective use against bacteria and yeast, the product must be left in contact with the skin for at least 30 seconds. After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking

	Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre and 3 post milking applications, per cow, per day (up to 5 applications in total) Apply a maximum of 10 ml product/cow/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

2.1.4.2 Use-specific instructions for use[5]

Meta SPC 1 - Deosan Activate BPF – concentrate

Use # 1 - Pre-milking disinfection, Manual dipping (concentrate)

Pre-milking
For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.
Apply directly to animal teats pre-milking via manual dipping method.
3 pre-milking applications, per animal, per day.
Apply a maximum of 10 ml product/ animal /application

Use # 2 – Pre-milking disinfection, Manual foaming (concentrate)

Pre-milking
For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

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

Apply directly to animal teats pre-milking via manual foaming application method.

3 pre-milking applications, animal, per day.

Apply a maximum of 5 ml product/ animal /application

Use # 3 Pre-milking disinfection, Manual spraying (concentrate)

Pre-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Apply directly to animal teats pre-milking via manual spraying application method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 15 ml product/ animal /application

Use # 4 - Post-milking disinfection, Manual dipping (concentrate)

Post-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Applied directly to animal teats post milking via manual dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 5 – Post-milking disinfection, Manual foaming (concentrate)

Post-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Applied directly to animal teats post milking via manual foaming method.

3 post milking applications, per animal, per day.

Apply a maximum of 5 ml product/ animal /application

Use # 6 Post-milking disinfection, manual spraying (concentrate)

Post-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Applied directly to animal teats post milking via manual spraying method.

3 post milking applications, per animal, per day.

Apply a maximum of 15 ml product/ animal /application

Use # 7 Post-milking disinfection, automatic spraying (concentrate)

Post-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Applied directly to animal teats post milking via automatic spraying method.

5 post milking applications, per animal, per day. Not to be combined with pre-milking disinfection.

Apply a maximum of 15 ml product/ animal /application

Use # 8 Post-milking disinfection, semi-automatic dipping (concentrate)

Post-milking

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Applied directly to animal teats post milking via semi-automatic dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 9 Pre and post-milking disinfection, manual dipping (concentrate)

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Pre-milking

Apply directly to animal teats pre-milking via manual dipping method.

3 pre milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Post-milking

Applied directly to animal teats post milking via manual dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 10 Pre and post-milking disinfection, manual foaming (concentrate)

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Pre-milking

Apply directly to animal teats pre-milking via manual foaming application method.

3 pre-milking applications, animal, per day.

Apply a maximum of 5 ml product/ animal /application

Post-milking

Apply directly to animal teats post-milking via manual foaming application method.

3 post milking applications, per animal, per day.

Apply a maximum of 5 ml product/ animal /application

Use # 11 Pre and post-milking disinfection, manual spraying (concentrate)

For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

Pre-milking

Apply directly to animal teats pre-milking via manual spraying application method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 15 ml product/ animal /application

Post-milking

Apply directly to animal teats post-milking via manual spraying application method.

3 post milking applications, per animal, per day.

Apply a maximum of 15 ml product/ animal /application

Meta SPC 2 - Deosan Activate BPF – RTU liquid

Use # 12 - Pre-milking disinfection, Manual dipping (RTU liquid)

Pre-milking

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Apply directly to animal teats pre-milking via manual dipping method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 13 – Pre-milking disinfection, Manual foaming (RTU liquid)

Pre-milking
Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
Apply directly to animal teats pre-milking via manual foaming application method.
3 pre-milking applications, per animal, per day.
Apply a maximum of 5 ml product/ animal /application

Use # 14 Pre-milking disinfection, Manual spraying (RTU liquid)

Pre-milking
Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
Apply directly to animal teats pre-milking via manual spraying application method.
3 pre-milking applications, per animal, per day.
Apply a maximum of 15 ml product/ animal /application

Use # 15 - Post-milking disinfection, Manual dipping (RTU liquid)

Post-milking
Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
Applied directly to animal teats post milking via manual dipping method.
3 post milking applications, per animal, per day.
Apply a maximum of 10 ml product/ animal /application

Use # 16 – Post-milking disinfection, Manual foaming (RTU liquid)

Post-milking
Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
Applied directly to animal teats post milking via manual foaming method.
3 post milking applications, per animal, per day.
Apply a maximum of 5 ml product/ animal /application

Use # 17 Post-milking disinfection, Manual spraying (RTU liquid)

Post-milking
Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
Applied directly to animal teats post milking via manual spraying method.
3 post milking applications, per animal, per day.
Apply a maximum of 15 ml product/ animal /application

Use # 18 Post-milking disinfection, automatic spraying (RTU liquid)

Post-milking

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Applied directly to animal teats post milking via automatic spraying method.

5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection.

Apply a maximum of 15 ml product/cow/application

Use # 19 Post-milking disinfection, semi-automatic dipping (RTU liquid)

Post-milking

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Applied directly to animal teats post milking via semi-automatic dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 20 Pre and post milking disinfection, manual dipping (RTU liquid)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Pre-milking

Apply directly to animal teats pre-milking via manual dipping method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Post-milking

Applied directly to animal teats post milking via manual dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 21 Pre and post milking disinfection, manual foaming (RTU liquid)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Pre-milking

Apply directly to animal teats pre-milking via manual foaming application method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 5 ml product/ animal /application

Post-milking

Applied directly to animal teats post milking via manual foaming method.
3 post milking applications, per animal, per day.
Apply a maximum of 5 ml product/ animal /application

Use # 22 Pre and post milking disinfection, manual spraying (RTU liquid)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Pre-milking
Apply directly to animal teats pre-milking via manual spraying application method.
3 pre-milking applications, per animal, per day.
Apply a maximum of 15 ml product/ animal /application

Post-milking
Applied directly to animal teats post milking via manual spraying method.
3 post milking applications, per animal, per day.
Apply a maximum of 15 ml product/ animal /application

Meta SPC 3 - Deosan Activate BPF – RTU gel

Use # 23 - Pre-milking disinfection, Manual dipping (RTU gel)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Pre-milking
Apply directly to animal teats pre-milking via manual dipping method.
3 pre-milking applications, per animal, per day.
Apply a maximum of 10 ml product/ animal /application

Use # 24 - Post-milking disinfection, Manual dipping (RTU gel)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Post-milking
Applied directly to animal teats post milking via manual dipping method.
3 post milking applications, per animal, per day.
Apply a maximum of 10 ml product/ animal /application

Use # 25 Post-milking disinfection, semi-automatic dipping (RTU gel)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Post-milking

Applied directly to animal teats post milking via semi-automatic dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Use # 26 Pre and post milking disinfection, manual dipping (RTU gel)

Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.

Pre-milking

Apply directly to animal teats pre-milking via manual dipping method.

3 pre-milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

Post-milking

Applied directly to animal teats post milking via manual dipping method.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/ animal /application

2.1.4.3 Use-specific risk mitigation measures

Meta SPC 1 Deosan Activate BPF – Concentrate - Professional Concentrate

Use # 1 – Pre-milking disinfection, manual dipping (concentrate)

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/post-milking disinfection

Use # 2 – Pre-milking disinfection, manual foaming (concentrate)

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/post-milking disinfection

Use # 3 – Pre-milking disinfection, manual spraying (concentrate)

Wear protective chemical resistant gloves during product handling phase (glove 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/post-milking disinfection

Use # 4 – Post-milking disinfection, manual dipping (concentrate)

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/post-milking disinfection

Use # 5 – Post-milking disinfection, manual foaming (concentrate)

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/post-milking disinfection

Use # 6 – Post-milking disinfection, manual spraying (concentrate)

Wear protective chemical resistant gloves during product handling phase (glove 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/post-milking disinfection

Use # 7 – Post-milking disinfection, automatic spraying (not to be combined with a pre-milking disinfection (concentrate)

See 2.1.5

Use # 8 – Post-milking disinfection, semi-automatic dipping (concentrate)

See 2.1.5

Use # 9 Pre and post-milking disinfection, manual dipping (concentrate)

See 2.1.5

Use # 10 Pre and post-milking disinfection, manual foaming (concentrate)

See 2.1.5

Use # 11 Pre and post-milking disinfection, manual spraying (concentrate)

Wear protective chemical resistant gloves during product handling phase (glove material

to be specified by the authorisation holder within the product information) Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn

Meta SPC 2 Deosan Activate BPF – RTU liquid - **Professional RTU Liquid**

Use # 12 Pre-milking disinfection, manual dipping (RTU liquid)

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/post-milking disinfection

Use # 13 – Pre-milking disinfection, manual foaming (RTU liquid)

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/post-milking disinfection

Use # 14 Pre-milking disinfection, manual spraying (RTU liquid)

Wear protective chemical resistant gloves during product handling phase (glove 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/post-milking disinfection

Use # 15 – Post-milking disinfection, manual dipping (RTU liquid)

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/post-milking disinfection

Use # 16 – Post-milking disinfection, manual foaming (RTU liquid)

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/post-milking disinfection

Use # 17 – Post-milking disinfection, manual spraying (RTU liquid)

Wear protective chemical resistant gloves during product handling phase (glove 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/post-milking disinfection

Use # 18 – Post-milking disinfection, automatic spraying (not to be combined with a pre-milking disinfection (RTU liquid)

See 2.1.5

Use # 19 – Post-milking disinfection, semi-automatic dipping (RTU liquid)

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/post-milking disinfection

Use # 20 – Pre and post milking disinfection, manual dipping (RTU liquid)

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

Use # 21 – Pre and post milking disinfection, manual foaming (RTU liquid)

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

Use # 22 – Pre and post milking disinfection, manual spraying (RTU liquid)

Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn

Meta SPC 3 Deosan Activate BPF – RTU gel (use)- Professional RTU Gel

Use # 23 – Pre-milking disinfection, manual dipping (RTU gel)

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/post-milking disinfection

Use # 24 – Post-milking disinfection, manual dipping (RTU gel)

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/post-milking disinfection

Use # 25 – Post-milking disinfection, semi-automatic dipping (RTU gel)

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/post-milking disinfection

Use # 26 – Pre and post-milking disinfection, manual dipping (RTU gel)

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

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

See 2.1.5.3

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

See 2.1.5.4

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

Meta SPC 1 Deosan Activate BPF – concentrate (use # 1-11)

24 month shelf life is supported Do not store above 40 °C

Meta SPC 2 Deosan Activate BPF – RTU liquid (use # 12-22)

24 month shelf life is supported Do not store above 30 °C

Meta SPC 3 Deosan Activate BPF – RTU gel (use # 23-26)

A 18 month shelf life is supported Do not store above 30 °C

2.1.5 General directions for use

2.1.5.1 Instructions for use[6]

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

Pre milking:
Apply product to full length of each teat.
For effective use against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds.
After the appropriate contact time, thoroughly remove the product, using a single service paper towel/cloth to ensure teats are clean and dry.
In use Iodine concentration of 3000mg/Kg (0.3% w/w)

Post milking:
Cover the full length of each teat with the product, immediately after milking.
To ensure sufficient contact time for post-milking application, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes)
In use Iodine concentration of 3000mg/Kg (0.3% w/w)

2.1.5.2 Risk mitigation measures

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

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

Inhalation: No known effects or symptoms in normal use.
Skin contact: No known effects or symptoms in normal use.
Eye contact: No known effects or symptoms in normal use.
Ingestion: No known effects or symptoms in normal use

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

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

Stability and reactivity:
Reactivity: No reactivity hazards known under normal storage and use conditions.
Chemical stability: Stable under normal storage and use conditions.

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

Possibility of hazardous reactions: No hazardous reactions known under normal storage and use conditions.
Conditions to avoid: None known under normal storage and use conditions.
Hazardous decomposition products: None known under normal storage and use conditions.
Environmental precautions:
Dike to collect larger liquid spills.
Contain and/or absorb spill with inert material, then place in suitable container.
Prevent run-off from entering drains, sewers or waterways.
Collect in closed and suitable containers for disposal.
Do not place spilled materials back into the original container.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers must be tripled rinsed prior to disposal
Paper towels used to dry animal teats and remove the product from them should be disposed of as normal/domestic waste.
Do not discharge undiluted product to sewers.

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

Store only in original, closed container
Protect from frost

2.1.6 Other information

Application codes

2.1.7 Packaging of the biocidal product

Type of packaging	Size/ volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Canister	1, 5, 20 L	White or natural f-HDPE Blue or natural HDPE	Screwed caps with foam gasket seals and pilferproof rings.	Professional	Yes. There were no adverse interactions between the products and HDPE packaging tested during ambient temperature storage. Extrapolation to f-HDPE canisters is acceptable.
Drum	200 L	White or natural f-HDPE Blue or	Screwed Din and/or Tri-sure caps closures.	Professional	Yes. There were no adverse interactions between the products and HDPE packaging

		natural HDPE			tested during ambient temperature storage. Extrapolation to f-HDPE drums is acceptable.
Intermediate bulk container	950 L	Natural or white f-HDPE Natural or white HDPE	Din sized screw caps with O-ring sealings.	Professional	Yes. There were no adverse interactions between the products and HDPE packaging tested during ambient temperature storage. Extrapolation to f-HDPE IBCs is acceptable.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 of this PAR

2.1.8.2 Access to documentation

The applicant has submitted a declaration of ownership from [redacted] This states that Diversey Operations Europe B.V; *"have propriety and ownership rights to the complete Iodine active substance dossiers submitted by the IRG for product types 3, 4 and 22 and own or have received access rights to the data included in the dossiers"*

2.1.8.3 Similar conditions of use

Communication D(2015)1091, dated 16th March 2015, from ECHA and addressed to Diversey Opeartions Europe B.V. states the following;

"The biocidal product family Deosan Activate Biocidal Product Family based on Iodine is deemed to be eligible for Union authorisation.

Reasons

No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product family Deosan Activate Biocidal Product Family based on Iodine 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"

This document can be found in section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product (family)

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

Meta SPC 1 - Deosan Activate BPF – concentrate

Table 3. Use # 1 – Pre-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual dipping method. Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking applications, per animal, per day. Apply a maximum of 10 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 2. Use # 2 – Pre-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual foaming method. Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking applications, per animal, per day. Apply a maximum of 5 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 3. Use # 3 – Pre-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre milking via manual spraying method.

	Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking applications, per animal, per day. Apply a maximum of 15 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 4. Use # 4 – Post-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual dipping method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted.

	3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 5. Use # 5 – Post-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual foaming method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 6. Use # 6 – Post-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an	Teat disinfectant, for direct application to lactating animals

exact description of the authorised use	post-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual spraying method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 7. Use # 7 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via automatic spraying method. Cover the full length of each teat with the product, immediately after milking.

	To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 8. Use # 8 – Post-milking disinfection, Semi-automatic dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 post milking applications, per animal, per day.

	Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 9. Use # 9 Pre and post-milking disinfection, Manual dipping (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual dipping method. For pre milking: Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Applied directly to animal teats post milking via manual dipping method. Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking and 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/animal/application

Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 10. Use # 10 Pre and post-milking disinfection, Manual foaming (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post-milking via manual foaming method. For pre-milking: Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking and 3 post milking applications, per animal, per day. Apply a maximum of 5 ml product/animal/application
Category(ies) of users	Professional

Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 11. Use # 11 Pre and post-milking disinfection, Manual spraying (concentrate)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual spraying method. For Pre-Milking: Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) For products containing 1.5% iodine this can be: Dilute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For products with another concentration this instruction should be adapted. 3 pre milking and 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/animal/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Meta SPC 2 - Deosan Activate BPF – RTU liquid

Table 12. Use # 12 Pre-milking disinfection, Manual dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual dipping methods. Pre-milking Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 13. Use # 13 – Pre-milking disinfection, Manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual foaming method. Pre-milking Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 14. Use # 14 Pre-milking disinfection, Manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]

	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre-milking via manual spraying method. Pre-milking Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 15. Use # 15 – Post-milking disinfection, Manual dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor

Application method(s)	Applied directly to animal teats post milking via manual dipping method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 16. Use # 16 – Post-milking disinfection, Manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual foaming method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not

	dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 17. Use # 17 – Post-milking disinfection, Manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual spraying method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do, not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 18. Use # 18 – Post-milking disinfection, Automatic spraying (not to be combined with a pre-milking disinfection (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via automatic spraying method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 49. Use # 19 – Post-milking disinfection, Semi-automatic dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of	Teat disinfectant, for direct application to lactating animals post milking

the authorised use	
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 20. Use # 20 – Pre and post milking disinfection, manual dipping (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via

	manual dipping methods. For pre-milking: Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking and 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 21. Use # 21 – Pre and post milking disinfection, manual foaming (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual foaming method.

	For pre-milking: Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time, do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre-milking and 3 post-milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 22. Use # 22 – Pre and post milking disinfection, manual spraying (RTU liquid)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual spraying method. For pre-milking Apply product to full length of each teat.

	[redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking: Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do, not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre and 3 post milking applications, per animal, per day. Apply a maximum of 15 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Meta SPC 3 - Deosan Activate BPF – RTU gel

Table 23. Use # 23 – Pre-milking disinfection, Manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre-milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre- milking via manual dipping application method. Pre-milking Apply product to full length of each teat.

	[redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre milking applications, per cow, per day. Apply a maximum of 10 ml product/cow/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 24. Use # 24 – Post-milking disinfection, Manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via manual dipping application methods. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not

	dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 25. Use # 25 – Post-milking disinfection, Semi-automatic dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats post milking via semi-automatic dipping application method. Post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

Table 26. Use # 26 – Pre and post-milking disinfection, manual dipping (RTU gel)

Product Type	PT3- Veterinary hygiene (disinfectant)
Where relevant, an exact description of the authorised use	Teat disinfectant, for direct application to lactating animals pre and post milking
Target organism(s) (including development stage)	[redacted]
Field(s) of use	Indoor
Application method(s)	Applied directly to animal teats pre and post milking via manual dipping application method. For pre-milking Apply product to full length of each teat. [redacted] After appropriate contact time, thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry. For post milking Cover the full length of each teat with the product, immediately after milking. To ensure sufficient contact time do not wipe product off teats.
Application rate(s) and frequency	In use Iodine concentration of 3000mg/Kg (0.3% w/w) Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. 3 pre and 3 post milking applications, per cow, per day. Apply a maximum of 10 ml product/cow/application
Category(ies) of users	Professional
Pack sizes and packaging material	1, 5 & 20 litre HDPE or f-HDPE canister 200 litre HDPE or f-HDPE drum 950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)

2.2.2 Physical, chemical and technical properties

The Deosan Activate biocidal product family is separated into three meta-SPC groups. The first meta-SPC contains 2 soluble concentrate (SL) products, the second meta-SPC contains 3 products that are ready to use liquids (AL) and the final meta-SPC contains one ready to use gel (water soluble gel, GW) product:

MSPC 1 (soluble concentrate, SL):
Lead products:
Deosan Activate Pre AG106
Deosan Activate Pre/Post Conc. AG218

MSPC 2 (ready to use liquids, AL-RTU):
Lead products:
Deosan Activate Pre RTU AG108
Deosan Activate Pre/Post AG217
Deosan Activate PVP Plus AG215

MSPC 3 (ready to use gel, GW-RTU):
Lead products:
Deosan Activate Barrier AG216

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

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Physical state at 20 °C and 101.3 kPa	Visual assessment	Deosan Activate Pre AG106: 1.5%	Liquid	[redacted] (2014), report no. S-2014-00026 AMI	Acceptable.
		Deosan Activate Pre/Post Conc AG218: 1.5%	Liquid	[redacted] (2015), report no, S-2014-03198 AMi	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
		Deosan Activate Pre RTU AG108: 0.3%	Liquid	SDS (2015)	Acceptable
		Deosan Activate Pre/Post AG217: 0.3%	Liquid	SDS (2015)	Acceptable
		Deosan Activate PVP Plus AG215: 0.3%	Liquid	SDS (2015)	Acceptable.
		Deosan Activate Barrier AG216: 0.3%	Liquid	[redacted] (2014), report no. S-2014-00023 AM	Acceptable.
Colour at 20 °C and 101.3 kPa	Visual assessment	Deosan Activate Pre AG106: 1.5%	Dark brown	[redacted] (2014), report no. S-2014-00026 AMI	Acceptable.
		Deosan Activate Pre/Post Conc AG218: 1.5%	Clear dark brown	[redacted] (2015), report no, S-2014-03198 AMi	Acceptable.
		Deosan Activate Pre RTU AG108: 0.3%	Clear dark brown	SDS (2015)	Acceptable.
		Deosan Activate Pre/Post AG217: 0.3%	Clear dark brown	SDS (2015)	Acceptable.
		Deosan Activate PVP Plus AG215: 0.3%	Clear dark brown	SDS (2015)	Acceptable.
		Deosan Activate Barrier AG216: 0.3%	Clear dark brown	[redacted] (2014), report no. S-2014-00023 AM	Acceptable.
Odour at 20 °C and 101.3 kPa	Olfactory assessment	Deosan Activate Pre AG106: 1.5%	Product specific.	SDS (2015)	Acceptable.
		Deosan Activate	No specific odour.	[redacted]	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
		Pre/Post Conc AG218: 1.5%		(2015), report no, S-2014-03198 AMi	
		Deosan Activate Pre RTU AG108: 0.3%	Product specific.	SDS (2015)	Acceptable.
		Deosan Activate Pre/Post AG217: 0.3%	Product specific.	SDS (2015)	Acceptable.
		Deosan Activate PVP Plus AG215: 0.3%	Product specific.	SDS (2015)	Acceptable.
		Deosan Activate Barrier AG216: 0.3%	Product specific.	SDS (2015)	Acceptable.
pH	CIPAC MT 75.3	Deosan Activate Pre AG106: 1.5%	Neat solution: 4.25 1 % diluted sample: 4.57	[redacted] (2014), report no. S-2014-00026 AMI	Acceptable, as pH is within the range 4-10 acidity or alkalinity are not required.
	CIPAC MT 75.3	Deosan Activate Pre/Post Conc AG218: 1.5%	Neat solution: 3.96 1 % dilution: 4.26	[redacted] (2015), report no, S-2014-03199 AMi	Acceptable, as the neat pH is < 4 acidity is required, see section below for results.
	Case	Deosan Activate Pre RTU AG108: 0.3%	Read across from Deosan Activate Pre AG106. As RTU AG108 is the diluted solution of AG106 it is expected that the pH values will be similar and most likely slightly higher.	IUCLID dossier, section 3.2	Acceptable, the products are suitably similar to extrapolate data.
	Case	Deosan Activate Pre/Post AG217: 0.3%	Read across from Deosan Activate Pre/Post Conc AG218. As RTU AG217 is similar to a diluted solution of AG218 is it expected that the pH values with be similar and most likely slightly higher.	IUCLID dossier, section 3.2	Acceptable, the products are suitably similar to extrapolate data.
	QATM P-004 (pH meter and glass electrode), equivalent	Deosan Activate PVP Plus AG215: 0.3%	Neat solution: 3.88	[redacted] 2018	Acceptable. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	to CIPAC MT 75.3				[redacted]
	CIPAC MT 75.3	Deosan Activate Barrier AG216: 0.3%	Neat solution: 4.22 1 % diluted sample: 4.79	[redacted] (2014), report no. S-2014-00023 AM	Acceptable, as pH is within the range 4-10 acidity or alkalinity are not required.
Acidity / alkalinity	CIPAC MT 191	Deosan Activate Pre/Post Conc AG218: 1.5%	Acidity: 0.458 % m/m as H_2SO_4	[redacted] (2015), report no, S-2014-03199 AMi	Acceptable. These data can also be extrapolated to product AG106 as the pH values and formulations are similar. As the pH data only show a slight decrease on storage acidity data has not been requested post storage.
Relative density / bulk density	OECD guideline 109	Deosan Activate Pre AG106: 1.5%	Density at 20 °C: 1.045 g/cm^3 Density at 40 °C: 1.043 g/cm^3	[redacted] (2014), report no. S-2014-000027 AM	Acceptable.
	OECD guideline 109	Deosan Activate Pre/Post Conc AG218: 1.5%	Density at 20 °C: 1.129 g/cm^3 Density at 40 °C: 1.125 g/cm^3	[redacted] (2015), report number S-2014-03200 AMi	Acceptable.
	Case	Deosan Activate Pre RTU AG108: 0.3%	Read across from Deosan Activate Pre AG106. As RTU AG108 is a diluted solution of AG106 the density can be extrapolated. A relative density of *ca.* 1.009 at 20 °C has been calculated.	IUCLID dossier, section 3.3	Acceptable, the products are suitably similar to extrapolate data.
	Case	Deosan Activate	Read across from Deosan Activate Pre/Post	IUCLID dossier,	Acceptable, the products are

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
		Pre/Post AG217: 0.3%	Conc AG218. As RTU AG217 is similar to a diluted solution of AG218 the density can be extrapolated. A relative dentistry of *ca.* 1.026 at 20 °C has been calculated.	section 3.3	suitably similar to extrapolate data.
	Case	Deosan Activate PVP Plus AG215: 0.3%	Read across from Deosan Activate Pre/Post Conc AG218. As RTU AG215 is similar to a diluted solution of AG218 the density can be extrapolated. A relative dentistry of *ca.* 1.026 at 20 °C has been calculated.	IUCLID dossier, section 3.3	Acceptable, the products are suitably similar to extrapolate data.
	OECD guideline 109	Deosan Activate Barrier AG216: 0.3%	Density at 20 °C: 1.025 g/cm^3 Density at 40 °C: 1.018 g/cm^3	[redacted] (2014), report no. S-2014-000024 AM	Acceptable.
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Visual assessment Validated method S-2013-03029AM-MdP Gravimetric OECD 114, CIPAC MT 192	Deosan Activate Pre AG106: 1.5%	<u>Appearance</u> Initial: Viscous brown liquid. After 8 weeks at 40 °C: Viscous brown liquid After 18 weeks at 30 °C: Viscous brown liquid. <u>Iodine content</u> Initial:1.424 % After 8 weeks at 40 °C: 1.281 % After 18 weeks at 30 °C: 1.350 % <u>Weight loss</u> After 8 weeks at 40 °C: 0.03 % After 18 weeks at 30 °C: 0.12 % <u>Viscosity (20 °C, 40 °C)</u> Initial: 10.133, 7.879 mm^2/s After 8 weeks at 40 °C: 8.868, 6.530 mm^2/s	[redacted] (2014), report number 2014/2AMi.	[redacted] Acceptable, no change in product appearance. Acceptable, [redacted] Acceptable, no significant change in product weight after accelerated storage. Acceptable, no significant change in viscosity after accelerated storage.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			After 18 weeks at 30 °C: 9.027, 6.776 mm^2/s No variation in the packaging was observed after accelerated storage.		Acceptable, but not strictly required. [redacted]
	CIPAC MT 46.3 Visual assessment Validated method S-2013-03029AM-MdP Gravimetric OECD 114, CIPAC MT 192	Deosan Activate Pre/Post Conc AG218: 1.5%	<u>Appearance</u> Initial: Clear dark brown viscous liquid. After 8 weeks at 40 °C: Clear dark brown viscous liquid. <u>Iodine content</u> Initial: 1.4 % After 8 weeks at 40 °C: 1.31 % <u>Weight loss</u> After 8 weeks at 40 °C: 0.01 % <u>Kinematic viscosity (20 °C, 40 °C)</u> Initial: 91.939, 40.910 mm^2/s After 8 weeks at 40 °C: 83.396, 34.452 mm^2/s No variation in the packaging was observed after accelerated storage.		[redacted] Acceptable, no change in product appearance. Acceptable, loss of iodine is 6.4 % after accelerated storage. Acceptable, no significant change in product weight. Acceptable, no significant change in kinematic viscosity. Acceptable but not strictly required. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
					[redacted]
	Case	Deosan Activate Pre RTU AG108: 0.3%	Read across from Deosan Activate Pre AG106. As RTU AG108 is a diluted solution of AG106 storage stability results nearly identical to those of the concentrate can be expected.	IUCLID dossier, section 3.4.1	Acceptable, the products are suitably similar to extrapolate data. [redacted]
	Case	Deosan Activate Pre/Post AG217: 0.3%	Read across from Deosan Activate Pre/Post Conc AG218. Since AG217 is similar to a diluted solution of AG218 it is expected that the storage stability results will be nearly identical to those of the concentrated product.	IUCLID dossier, section 3.4.1	Acceptable, the products are suitably similar to extrapolate data. [redacted]
	Case	Deosan Activate PVP Plus AG215: 0.3%	Read across from Deosan Activate Pre/Post Conc AG218. Since AG215 is similar to a diluted solution of AG218 it is expected that the storage stability results will be nearly identical to those of the concentrated product.	IUCLID dossier, section 3.4.1	Acceptable, the products are suitably similar to extrapolate data. [redacted]
	CIPAC MT 46.3 Visual assessment	Deosan Activate Barrier AG216: 0.3%	<u>Appearance</u> Initial: Very viscous brown liquid.	[redacted] (2014), report number 2014/1 AMi	[redacted] Acceptable, no change in

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			After 8 weeks at 40 °C: Very viscous brown liquid. After 18 weeks at 30 °C: Very viscous brown liquid.		product appearance.
	Validated method S-2013-03029AM-MdP		<u>Iodine content</u> Initial: 0.287 % After 8 weeks at 40 °C: 0.233 % After 18 weeks at 30 °C: 0.261 %		Acceptable, [redacted]
	Gravimetric		<u>Weight loss</u> After 8 weeks at 40 °C: 1.20 % After 18 weeks at 30 °C: 1.36 %		Acceptable, no significant change in product weight after accelerated storage.
	OECD 114, CIPAC MT 192		<u>Viscosity (20 °C, 40 °C)</u> Initial: 1268.3, 1200.8 mPa.s After 8 weeks at 40 °C: 1202.2, 1129.1 mPa.s After 18 weeks at 30 °C: 1226.7, 1149.4 mPa.s		Acceptable, no significant change in viscosity after accelerated storage.
			No variation in the packaging was observed after accelerated storage.		Acceptable, but not strictly required. pH data were not provided, see long term storage for further details.
Storage stability		Deosan Activate	The sample was stored for 24 months in 1 L	[redacted]	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
test – **long term storage at ambient temperature**		Pre AG106: 1.5%	black HDPE bottle at 25 °C, the sample was analysed at 3, 6, 12, 18 and 24 months however only the relevant data are presented.	(2016), report number 2014/3 AM	
	Visual assessment		<u>Appearance</u> Initial: Viscous brown liquid After 24 months: Viscous brown liquid		Acceptable, no change in product appearance after storage.
	Validated method S-2013-03029AM-MdP		<u>Iodine content</u> Initial: 1.42 %long term [redacted] After 24 months: 1.28 %		Acceptable [redacted]
	Gravimetric		<u>Weight loss</u> After 12 months: 0.051 % After 18 months: 0.067 % After 24 months: - (deviation in study plan)		Acceptable, [redacted]
	OECD 114 CIPAC MT 192		<u>Viscosity (20 °C, 40 °C)</u> Initial: 10.132, 7.876 mm^2/s After 24 months: 9.100, 6.370 mm^2/s		Acceptable, no significant change in viscosity after 24 months ambient storage.
	CIPAC MT 185		<u>Wet sieve</u> After 24 months: No residue on the 75 µm sieve.		Acceptable, [redacted]
	CIPAC MT		<u>Dilution stability</u>		Acceptable, no separation

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	41 Visual assessment In house method – equivalent to CIPAC MT 75.3		After 24 months: No separation. <u>Packaging</u> No variation in 1L HDPE packaging observed between initial and 24 months storage. <u>pH</u> Initial: 3.87 After: 3.49	[redacted] 2016	observed after storage for 24 months. [redacted] Acceptable, HDPE packaging remained stable after 24 months storage. Acceptable, a [redacted]
	Case In house method – equivalent to CIPAC MT 75.3	Deosan Activate Pre/Post Conc AG218: 1.5%	Based on the comparison of the 40°C accelerated tests for the two concentrates, "Deosan Activate Pre/Post Conc." is expected to be at least as stable as "Deosan Activate Pre AG106". <u>pH</u> Initial: 4.00 After: 3.88	IUCLID dossier, section 3.4.1 [redacted] 2016	Acceptable, AG218 was more stable for 8 weeks at 40 °C compared to AG106. Therefore long term storage stability data for AG106 can be extrapolated to support AG218. Acceptable, [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
					[redacted]
	Case	Deosan Activate Pre RTU AG108: 0.3%	Read across from Deosan Activate PVP Plus AG215.	IUCLID dossier, section 3.4.1	Acceptable, the products are suitably similar to extrapolate data.
	Case	Deosan Activate Pre/Post AG217: 0.3%	Read across from Deosan Activate PVP Plus AG215.	IUCLID dossier, section 3.4.1	Acceptable, the products are suitably similar to extrapolate data.
	Visual assessment DM-033, redox titration with sodium thiosulphate equivalent to the validated method QATM P-004 (pH meter and glass electrode), equivalent to CIPAC MT 75.3	Deosan Activate PVP Plus AG215: 0.3%	The sample was stored for 2 years in 20 L HDPE packaging at room temperature. The sample was analysed (a.s. content) at 3, 6, 10, 17 and 23 months. <u>Appearance</u> Initial: Dark brown liquid. After 23 months: No change. <u>Iodine content</u> Initial: 0.30 % [redacted] After 23 months: 0.27 % <u>pH</u> Initial: 3.88 After 23 months: 3.70	[redacted] 2018 (R4BP3 ref:)	Acceptable, no change in product appearance after 2 years storage. Acceptable, [redacted] Acceptable, [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			[redacted] Packaging and weight No variation, discolouration or deformation of the 20 L HDPE packaging was observed. The weight of the stored can was as expected 21.6 kg (density of the product is 1.03 x 20 L = 20.6 kg and 1.0 kg packaging material).		[redacted] Acceptable, the HDPE packaging remains stable after 2 years storage. [redacted]
	Visual assessment Validated method S-2013-03029AM-MdP	Deosan Activate Barrier AG216: 0.3%	The sample was stored for 24 months in 1 L black HDPE bottles at 25 °C, the sample was analysed at 3, 6, 12, 18 and 24 months however only the relevant data are presented. Appearance Initial: Very viscous brown liquid After 24 months: Very viscous brown liquid Iodine content Initial: 0.287% [redacted] After 18 months: 0.237 % [redacted] %	[redacted] A. (2016), report number 2014/4 Ami	Acceptable, no change in product appearance after 24 months storage. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
					[redacted] the applicant has provided efficacy studies to support a longer shelf life (18 months) for the product. Please see the efficacy section (section 2.2.5) for the outcome for the evaluation of the relevant studies.
	Gravimetric		<u>Weight loss</u> After 12 months: 0.047 % After 18 months: 0.069 % After 24 months: - (deviation in study plan)		Acceptable [redacted]
	OECD 114 CIPAC MT 192		<u>Viscosity (20 °C, 40 °C)</u> Initial: 1265.8, 1201.6 mPa.s After 24 months: 1149.0, 1043.5 mPa.s		Acceptable, no significant change in viscosity after 24 months storage.
	CIPAC MT 185		<u>Wet sieve</u> After 24 months: No residue on the 75 µm sieve.		Acceptable [redacted]
	Visual assessment		<u>Packaging</u> No variation in 1 L HDPE packaging observed between initial and 24 months storage.		Acceptable, HDPE packaging remained stable after 24 months storage.
	In house method – equivalent to CIPAC MT		pH (neat) Initial: 3.94 After 24 months: 3.50	[redacted] 2017)	Acceptable. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	75.3				[redacted]
Storage stability test – **low temperature stability test for liquids**	Case	All products.	Such a study is not required due to label claim: protect from frost.	IUCLID dossier, section 3.4.1	Acceptable, the labels state 'protect from frost'.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Case	All products.	Impact on light can be excluded due to lightproof packaging.	IUCLID dossier, section 3.4.2	Acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Case	Deosan Activate Pre AG106: 1.5%	[redacted] Based on these results, it is concluded that temperatures above 40 °C should be avoided. Humidity: The product is packaged in sealed containers which do not allow access of	IUCLID dossier, section 3.4.2	Acceptable. The label should state "Do not store at temperatures above 40 °C".

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
			humidity. [redacted]		
	Case	Deosan Activate Pre/Post Conc AG218: 1.5%	[redacted] It is concluded that temperatures above 40 °C should be avoided. Humidity: The product is packaged in sealed containers which do not allow access of humidity. [redacted]		Acceptable. The label should state "Do not store at temperatures above 40 °C".
	Case	Deosan Activate Pre RTU AG108: 0.3% Deosan Activate Pre/Post AG217: 0.3% Deosan Activate PVP Plus AG215: 0.3%	Temperature: read across to accelerated test for "Deosan Activate Pre AG106": avoid temperatures above 40 °C. However as accelerated storage data have not been provided for this meta-SPC the maximum storage temperature should be 30 °C. Humidity: The product is packaged in sealed containers which do not allow access of humidity. Furthermore, since the product is water-based, access of humidity would be irrelevant.		Acceptable, [redacted] The labels should state "Do not store at temperatures above 30 °C".

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	Case	Deosan Activate Barrier AG216: 0.3%	Temperature: Based on the accelerated test results (8.9% decrease in iodine assay content within 18 weeks at 30°C), it is concluded that temperature above 30°C should be avoided. Humidity: The product is packaged in sealed containers which do not allow access of humidity. Furthermore, since the product is water-based, access of humidity would be irrelevant.		Acceptable. The label should state "Do not store at temperatures above 30 °C". [redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	All products in the BPF.	-	-	See long term storage above. No adverse effects observed between the product and HDPE packaging.
Persistent foaming	Case CIPAC MT 47.2	Deosan Activate Pre AG106: 1.5% Deosan Activate Pre/Post Conc AG218: 1.5%	According to the Guidance on information requirements, this test is not required when the product is intended to be for foam application. Therefore the test is not applicable. Data was presented showing that the products form stable foam both before and after storage. [redacted]	IUCLID dossier, section 3.5 [redacted] (2016) [redacted] (2016a)	Acceptable, persistent foam data are not required as the product is intended for foam application. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	In house visual assessment		[redacted]		
	Case	Deosan Activate Pre RTU AG108: 0.3% Deosan Activate Pre/Post AG217: 0.3% Deosan Activate PVP Plus AG215: 0.3% Deosan Activate Barrier AG216: 0.3%	[redacted]	IUCLID dossier, section 3.5	Acceptable, data are not required as the products are ready to use formulations and are intended to be used for foam applications.
Physical compatibility	Case	All products in the BPF.	Not applicable since none of the products in the biocidal product family are recommended to be used in combination with other products.	IUCLID dossier, section 3.6	Acceptable.
Chemical compatibility	Case	All products in the BPF.	Not applicable since none of the products in the biocidal product family are recommended to be used in combination with other products.	IUCLID dossier, section 3.6	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Degree of dissolution and dilution stability	CIPAC MT 41	Deosan Activate Pre AG106: 1.5%	No separated material present after 18 hours at 20 °C.	[redacted] (2014), report number S-2014-00030 AM	Acceptable.
		Deosan Activate Pre/Post Conc AG218: 1.5%	No separated material present after 18 hours at 20 °C.	[redacted] (2015), study number S-2014-03203 AMi	Acceptable.
	Case	Deosan Activate Pre RTU AG108: 0.3% Deosan Activate Pre/Post AG217: 0.3% Deosan Activate PVP Plus AG215: 0.3% Deosan Activate Barrier AG216: 0.3%	These products are ready to use liquids or gel. Therefore testing the degree of dissolution and dilutions stability is not applicable.	IUCLID dossier, section 3.7	Acceptable.
Surface tension	EU method A.5 (Du Noüy ring method)	Deosan Activate Pre RTU AG108: 0.3% Deosan Activate Barrier AG216: 0.3% Deosan Activate Pre/Post Conc AG218: 1.5%	AG108 undiluted at 20 °C = 31.02 mN/m AG216 undiluted at 20 °C = 31.13 mN/m AG218 undiluted at 20 °C = 27.99 mN/m All three tested products are therefore considered as surface active.	[redacted] 2018,	Acceptable. Surface tension has been determined on three products which were chosen as they contain the highest and lowest levels of surfactants, emollients and thickeners. Therefore these data can be used to support the whole BPF. [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
					[redacted] are required at this time. All products in the BPF are considered surface active.
Viscosity	OECD 114, CIPAC MT 192	Deosan Activate Pre AG106: 1.5%	Dynamic viscosity 20 °C: 10.532 mPa s 40 °C: 8.159 mPa s Kinematic viscosity 20 °C: 10.136 mm^2/s 40 °C: 7.883 mm^2/s	[redacted] (2014), report number S-2014-00031AM	Acceptable. [redacted]
	OECD 114, CIPAC MT 192	Deosan Activate Pre/Post Conc AG218: 1.5%	Dynamic viscosity 20 °C: 103.432 mPa s 40 °C: 45.381 mPa s Kinematic viscosity 20 °C: 91.939 mm^2/s 40 °C: 40.701 mm^2/s	[redacted] (2015), report number S-2014-03204AMi	Acceptable. [redacted]
	OECD 114	Deosan Activate Pre RTU AG108: 0.3%	Dynamic viscosity 20 °C: 1.835 mPa s 40 °C: 1.207 mPa s Kinematic viscosity 20 °C: 1.819 mm^2/s 40 °C: 1.196 mm^2/s	[redacted] (2015)	Acceptable. [redacted]
	OECD 114	Deosan Activate Pre/Post AG217: 0.3%	Dynamic viscosity 20 °C: 3.065 mPa s 40 °C: 0.604 mPa s Kinematic viscosity 20 °C: 3.005 mm^2/s 40 °C: 0.591 mm^2/s	[redacted] (2015a)	Acceptable [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
	OECD 114	Deosan Activate PVP Plus AG215: 0.3%	Dynamic viscosity 20 °C: 9.194 mPa s 40 °C: 6.037mPa s Kinematic viscosity 20 °C: 8.926 mm^2/s 40 °C: 5.861 mm^2/s	[redacted] (2015b)	Acceptable. [redacted]
	OECD 114, CIPAC MT 192	Deosan Activate Barrier AG216: 0.3%	Rotational viscosity 20 °C: = 1266.5 mPa.s 40 °C: = 1201.1 mPa.s	[redacted] (2014), report number S-2014-00025AM	Acceptable.

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

The physical, chemical and technical properties of the Deosan Activate product family are acceptable for the three formulation types, soluble concentrate, ready to use liquid and water soluble gel (ready to use), and therefore each meta-SPC. For a number of properties, data for the ready to use liquids can be read across from the concentrated products. Therefore the data provided are sufficient to support the BPF requested (see confidential annex for details).

Accelerated storage data for both the concentrated products were acceptable, therefore long term storage data were only collected for one product – Deosan Activate Pre AG106. These data can be used to support the storage stability (shelf life of 24 months) for the other concentrate product and therefore the whole meta-SPC.

Long term storage stability data were provided for product Deosan Activate PVP Plus AG215 supporting a shelf life of 24 months. These data can be extrapolated to support all products in meta-SPC 2.

Data were provided for the ready to use gel for both accelerated and long term storage. After 24 months the iodine content decreased by 24 %. Based on the storage stability data alone, a shelf life of 6 months is supported. It is noted that the applicant has provided efficacy studies which support a longer shelf life (18 months) for the product. Please see the efficacy section (section 2.2.5) for the outcome for the evaluation of the relevant studies.

Where the active substance content decreases by > 10 % during the storage stability study, it is required to investigate, in addition to whether the product is still efficacious, whether any compounds are formed that may influence the risk assessment e.g. hazardous metabolites. Iodine is a common oxidising agent. Generally iodine oxidises a compound to form iodide and an oxidised compound. The oxidised compounds would be expected to be hard to identify, and unlikely to pose a significant risk. Iodide would also not cause a significant risk. Therefore, no additional work is necessary to further identify the breakdown products.

There were no observations of degradation for the HDPE packaging in all cases. The following shelf lives and maximum storage temperatures are therefore supported:

MSPC 1: 24 months, maximum temperature 40 °C
MSPC 2: 24 months, maximum temperature 30 °C
MSPC 3: 18 months, maximum temperature 30 °C

All other properties, such as, appearance, viscosity and dilution stability were acceptable before and after long term storage.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
Explosives	Case	All products	The products do not contain any component which has explosive properties. Therefore, the products cannot be expected to have explosive properties.	IUCLID dossier, section 4.1	Acceptable, all products of the family would not be classified as explosive.
Flammable gases	Case	All products	Not applicable. The products are not flammable gases.	IUCLID dossier	Acceptable.
Flammable aerosols	Case	All products	Not applicable. The products are not flammable aerosols.	IUCLID dossier	Acceptable.
Oxidising gases	Case	All products	Not applicable. The products are not oxidising gases.	IUCLID dossier	Acceptable.
Gases under	Case	All products	Not applicable. The products are not gases	IUCLID dossier	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
pressure			under pressure.		
Flammable liquids	Case	All products	Not applicable. None of the products contain components which are classified as flammable.	IUCLID dossier, section 4.2	Acceptable, all products of the family would not be classified as flammable.
Flammable solids	Case	All products	Not applicable. The products are not solid.	IUCLID dossier	Acceptable.
Self-reactive substances and mixtures	Case		Not applicable. None of the components is classified as a self-reacting substance or mixture.	IUCLID dossier	Acceptable.
Pyrophoric liquids	Case	All products	Not applicable. None of the components is classified for having pyrophoric properties.	IUCLID dossier	Acceptable.
Pyrophoric solids	Case	All products	Not applicable. None of the components of the products is classified as a pyrophoric solid.	IUCLID dossier	Acceptable.
Self-heating substances and mixtures	Case	All products	Not applicable. None of the components of the product is classified as self-heating.	IUCLID dossier	Acceptable.
Substances and mixtures which in contact with water emit flammable gases	Case	All products	Not applicable. None of the components of the product is classified as a substance and mixtures which in contact with water emits flammable gases.	IUCLID dossier	Acceptable.
Oxidising liquids	Case	All products	Not applicable. None of the components of the products is classified as an oxidising liquid.	IUCLID dossier, section 4.4	Acceptable, all products of the family would not be classified as oxidising.
Oxidising solids	Case	All products	Not applicable. None of the components of the products is classified as an oxidising solid.	IUCLID dossier	Acceptable.
Organic peroxides	Case	All products	Not applicable. None of the components of the products is classified as an organic peroxide.	IUCLID dossier	Acceptable.
Corrosive to metals	Transport of Dangerous Goods, Manual of	Pre/Post Conc AG218: 1.5%	Three aluminium and three steel coupons were used to determine the corrosion activity of the product. Each coupon was varied in position, on fully immersed into the product, one half	[redacted] 2018	Acceptable. Corrosivity to metal has been determined for the worst case product, AG218. This product has the

<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><th>UK CA comments</th></tr>
<tr><td></td><td>Tests and Criteria, Part III, Section 37</td><td></td><td>immersed and one above the product. The test was carried out for 7 days with a test temperature of 55 °C.

Results of aluminium coupons after 7 days
<table>
<tr><td>Position</td><td>Mass before test (g)</td><td>Mass after test (g)</td><td>Mass loss (%)</td></tr>
<tr><td>Full</td><td>5.4740</td><td>5.4245</td><td>0.9043</td></tr>
<tr><td>Half</td><td>5.4618</td><td>5.3558</td><td>1.9408</td></tr>
<tr><td>Above</td><td>5.4815</td><td>5.4476</td><td>0.6184</td></tr>
</table>
Results of steel coupons after 7 days
<table>
<tr><td>Position</td><td>Mass before test (g)</td><td>Mass after test (g)</td><td>Mass loss (%)</td></tr>
<tr><td>Full</td><td>15.2538</td><td>14.7961</td><td>2.9996</td></tr>
<tr><td>Half</td><td>15.2308</td><td>14.7255</td><td>3.3172</td></tr>
<tr><td>Above</td><td>15.1665</td><td>15.2081</td><td>-0.2743*</td></tr>
</table>
*This coupon actually gained weight due to build-up of corroded metals.

Based on the laboratory results it can be concluded that the product is not corrosive to both aluminium and steel metals.</td><td></td><td>lowest pH value and the joint highest iodine content. This product is not considered corrosive to metals, therefore the same non-classification can be applied to the whole BPF.</td></tr>
<tr><td>Auto-ignition temperatures of products (liquids and gases)</td><td>Case</td><td>All products</td><td>Autoignition can be excluded since the products do not contain flammable substances or mixtures.</td><td>IUCLID dossier</td><td>Acceptable.</td></tr>
<tr><td>Relative self-ignition</td><td>Case</td><td>All products</td><td>Not applicable, since the products do not contain flammable substances or mixtures.</td><td>IUCLID dossier</td><td>Acceptable.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	UK CA comments
temperature for solids					
Dust explosion hazard	Case	All products	Not applicable. All products are water based, liquid products.	IUCLID dossier	Acceptable.

Conclusion on the physical hazards and respective characteristics of the product
None of the products of the Deosan Activate biocidal product family are classified for physical hazards. Therefore, a non-classification for each product of the BPF is acceptable.

2.2.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The sources of the active substances are the same as those considered for inclusion in the Union list of approved active substances or have been considered technically equivalent. Therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required.

Analytical methods for the active substance in the biocidal product

The method of determining the concentration of iodine in all members of the biocidal product family is a titration against sodium thiosulphate. This is a well-documented analytical method that is specific to iodine.

Samples are prepared for analysis by adding a known quantity of the test item (5 g for concentrated products, 15 g for RTU liquid and gel, equivalent to *ca.* 70 mg and 45 mg iodine respectively) to a 250 mL flask. To this 50 mL water, 1 mL diluted glacial acetic acid (12 mL glacial acetic acid in 100 mL water) and 1 g potassium iodide were added. The solution was titrated with sodium thiosulphate 0.1 N. Some drops of starch solution indicator were added and the titration continued until complete discolouration of the solution occurred. The iodine content can then be calculated based on the volume of sodium thiosulphate.

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**	**LOQ**	**Recovery fortification level**	**Recoveries %**	**Repeatability %RSD (n)**	**Linearity**	**Specificity**	**Reference**
Iodine in Deosan Activate Pre AG106	Titration with sodium thiosulphate (0.1N)	38 mg	38 mg (*ca.* 50 %) 76 mg (*ca.* 100 %) 114 mg (*ca.* 150 %)	98.8, 99.5 (99.2) 97.8, 98.1 (98.0) 97.3, 97.7 (97.5)	RSDr = 0.25 % (6) for a mean iodine content of 1.425 % w/w Acceptable Horwitz %RSD = 2.54 %	39.7 – 119.2 mg iodine (*ca.* 50 – 150 % nominal content) R^2 = 0.9994 n = 5	Blank and placebo did not consume any titrant. The placebo showed an interference of less than 3 %.	[redacted] (2013), report number S-2013-03029 AMi
Iodine in Deosan Activate Pre / Post Conc. AG 218	Titration with sodium thiosulphate (0.1N)	38 mg	38 mg (*ca.* 50 %) 75 mg (*ca.* 100 %) 113 mg (*ca.* 150 %)	98.3, 100.4 (99.4) 99.0, 100.4 (99.7) 99.7, 101.0 (100.4)	RSDr = 1.17 % (6) for a mean iodine content of 1.42 % w/w Acceptable Horwitz %RSD = 2.54 %	37.5 – 112.5 mg iodine (*ca.* 50 – 150 % nominal content) R^2 = 0.9999 n = 5	Blank and placebo did not consume any titrant.	[redacted] (2015), report number S-2014-03206 AMi
Iodine in Deosan Activate Pre RTU AG108	Titration with sodium thiosulphate (0.1N)	The formulation of "Deosan Activate Pre RTU" is very similar to the formulation of the product "Deosan Activate Pre/Post AG217". For specific details please see the confidential annex. Since the formulation can be considered to be almost identical, the analytical method for titrimetric quantification of the active ingredient iodine in the product "Deosan Activate Pre/Post AG217" is expected to be specific, linear, precise and accurate also for the product formulation "Deosan Activate Pre RTU".						
Iodine in Deosan Activate Pre/Post AG217	Titration with sodium thiosulphate (0.1N)	See "*Deosan Activate Barrier AG216"*	See "*Deosan Activate Barrier AG216"*	See "*Deosan Activate Barrier AG216"*	RSDr = 0.90 % (3) for a mean iodine content of 0.292 % w/w. Acceptable Horwitz %RSD =3.23 %	See "*Deosan Activate Barrier AG216"*	Blank and placebo did not consume any titrant. The placebo showed an interference of less than 3 %.	[redacted] (2013), report number S-2013-03031 AMi
Iodine in Deosan Activate PVP Plus AG215	Titration with sodium thiosulphate (0.1N)	See "*Deosan Activate Barrier AG216"*	See "*Deosan Activate Barrier AG216"*	See "*Deosan Activate Barrier AG216"*	RSDr = 2.5 % (3) for a mean iodine content of 0.286 % w/w. Acceptable Horwitz	See "*Deosan Activate Barrier AG216"*	Blank and placebo did not consume any titrant. The placebo showed an	[redacted] (2013), report number S-2013-03030 AMi

					%RSD =3.24 %		interference of less than 3 %.	
Iodine in Deosan Activate Barrier AG216	Titration with sodium thiosulphate (0.1N)	22 mg	22 mg (*ca.* 50 %) 45 mg (*ca.* 100 %) 68 mg (*ca.* 150 %)	100.8, 101.0 (100.9) 99.4, 101.0 (100.2) 99.9, 102.0 (101.0)	RSDr = 0.63 % (6) for a mean iodine content of 0.280 % w/w. Acceptable Horwitz %RSD =3.25 %	22.6 – 67.9 mg iodine (*ca.* 50 – 150 % nominal content) R^2 = 0.9997 n = 5	Blank and placebo did not consume any titrant. The placebo showed an interference of less than 3 %.	[redacted] (2013), report number S-2013-03028 AMi

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

Methods of analysis for the determination of iodine residues in air and water have previously been evaluated at EU level and accepted for BPR inclusion.

The following endpoints for methods of analysis for the determination of residues in food/feed of animal origin were presented in the CAR:

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

Methods for detection in soil were not required as the as the PECs calculated for soil was low compared to the natural background concentration and as iodine is not classified as toxic or highly toxic.

Methods for detection in food/feed of plant origin are not required due to a lack of exposure via intended uses.

For body fluids and tissues methods are not required as the active substance is not considered toxic.

Therefore, concerning product authorisation no further consideration is required.

Conclusion on the methods for detection and identification of the product
The analytical method for the detection of iodine is acceptable for all members of the biocidal product family. Full validation data have been provided for both concentrate products (AG106 and AG218) and the ready to use gel (AG216). From these data it is possible to also validate the method for iodine detection in the three RTU liquid products, along with the precision and specificity data specifically provided for these products. The method is therefore considered to be fit for the intended purpose. The monitoring methods for air, water and food/feed animal origin have previously been evaluated at EU level and accepted for inclusion in the Union list of approved active substances. The monitoring methods for soil, food/feed of plant origin and animal/human body fluids/tissue are not relevant for the Deosan Activate biocidal product family.

Conclusion

CHEMISTRY
DECISION Under Regulation (EU) No 528/2012 a **union authorisation may be recommended** for the Deosan Activate product family. **DATA REQUIRMENTS FOR POST AUTHORISATION** None. **CLASSIFICATION** A non-classification is acceptable for all three meta-SPCs, from a chemistry perspective. **LABEL AMENDMENTS** Please alter the temperature restriction text for all products to state "Do not store at temperatures above 40 °C" for meta-SPC 1 and "Do not store at temperatures above 30 °C" for meta-SPCs 2 and 3.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The Deosan Activate Biocidal Family contains products with in use concentration of 0.3% free iodine. The products are for use in product type 3 for teat disinfection and are for professional use only.

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

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

2.2.5.3 Effects on target organisms, including unacceptable suffering

The products are used pre and post-milking and are applied to the teats by dipping, foaming or spraying. The teat is dipped or sprayed up its full length with the diluted or neat product (containing 0.3% w/w available iodine), a minimum contact time of 30 seconds for pre-milking applications is stipulated then the teats can be wiped and dried.

2.2.5.4 Mode of action, including time delay

The applicant has provided the following statement:

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

2.2.5.5 Efficacy data

Studies considered to be of limited or no evidential value are shaded grey in the table below.

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfection of lactating animals' teats. Phase 2 Step 1 (EN1656) Bactericidal	Deosan Activate Pre AG106 (MetaSPC1)	Bacteria (*S. aureus, S. uberis, E.coli)*	The EN1656 standard protocol was followed. [redacted]	When a contact time of 15 seconds was used, for all the test organisms, a greater than 5 log reduction (the pass criterion for the standard) was observed for the 10% solutions tested or lower.	[redacted] (2014) (Bacteria) (Report No:D51-2013)
	Deosan Activate Pre/Post Conc. AG218 (MetaSPC1)		The EN1656 standard protocol was followed. [redacted]		[redacted] (2014) (Bacteria) (Report No:D73-2013)
	Deosan Activate Pre/Post AG217 (MetaSPC2)		The EN1656 standard protocol was followed. [redacted]		[redacted] (2014) (Bacteria) (Report No:D54-2013)
	Deosan Activate PVP Plus AG215 (MetaSPC2)		The EN1656 standard protocol was followed [redacted]		[redacted] (2014) (Bacteria) (Report No:D52-2013)

			[redacted]		
	Deosan Activate Barrier AG216 (MetaSPC3)		The EN1656 standard protocol was followed. [redacted]		[redacted] (2014) (Bacteria) (Report No:D53-2013)
Disinfection of lactating animals' teats. Phase 2 Step 1 (EN1657) Yeasticidal	Deosan Activate Pre AG106 (MetaSPC1)	Yeast (*C. albicans*)	The EN1657 standard protocol was followed [redacted]	When a contact time of 15 seconds was used, a greater than 4 log reduction (the pass criterion for the standard) was observed for the 5% solution tested.	[redacted] (2014) (Yeast) (Report No:D51-2014)
	Deosan Activate Pre/Post Conc. AG218 (MetaSPC1)		The EN1657 standard protocol was followed. [redacted]		[redacted] (2014) (Yeast) (Report No:D73-2014)
	Deosan Activate Pre/Post AG217 (MetaSPC2)		The EN1657 standard protocol was followed. [redacted]		[redacted] (2014) (Yeast) (Report No:D54-2014)
	Deosan Activate PVP Plus AG215 (MetaSPC2)		The EN1657 standard protocol was followed [redacted]		[redacted] (2014) (Yeast) (Report No:D52-2014)

	Deosan Activate Barrier AG216 10% (MetaSPC3)		The EN1657 standard protocol was followed.		(2014) (Yeast) (Report No:D53-2014)
				When a contact time of 5 minutes was used, a greater than 4 log reduction (the pass criterion for the standard) was observed for the 80% solution tested.	(2015) (Report No: D15L0445MV)
				When a contact time of 1 minute was used, a greater than 4 log reduction was observed for the 80% solution tested.	(2015) (Report No: D15L0278MV)
Disinfection of lactating animals' teats. Phase 2 Step 2 (Diversey – Sealed Air)	Deosan Activate Pre AG106 (MetaSPC1) Deosan Activate Pre/Post Conc. AG218 (MetaSPC1) Deosan Activate Pre/Post AG217 (MetaSPC2) Deosan Activate PVP Plus AG215 (MetaSPC2) Deosan Activate Barrier AG216 (MetaSPC3)	Bacteria (*S. aureus*) Yeast (*C. albicans*)	Testing based on EN14349 and EN16437	Bacteria – all products When a contact time of 30 seconds was used, a greater than 3 log reduction was observed for the 100% solution tested. When a contact time of 1 minute was used, a greater than 4 log reduction was observed for the 50, 80 and 100% solutions tested. When a contact time of 5 minutes was used, a greater than 4 log reduction was observed for the 80 and 100% solution tested.	(2016) (Report No: EN16437_200916_BH)

			[redacted]	Yeast – all products When a contact time of 30 seconds was used, a greater than 4 log reduction was observed for the 50, 80 and 100% solutions tested. When a contact time of 5 minutes was used, a greater than 4 log reduction was observed for the 80 and 100% solutions tested.	
Disinfection of lactating animals' teats. Phase 2 Step 2 (LHM Microbiology Expert)	Deosan Activate Pre AG106 (MetaSPC1)	Bacteria (*S. aureus*) Yeast (*C. albicans*)	Testing based on EN14349 and EN16437 [redacted]	Bacteria – all products When a contact time of 1 minute was used, a greater than 4 log reduction was observed for the 100% solution tested. (Except for in the tests conducted using Deosan Activate PVP Plus AG215 were a <3.91 log reduction was observed but difficulties with recovering bacteria from the skin were noted.) When a contact time of 5 minutes was used, a greater than 4 log reduction was observed for the 80 and 100% solutions tested. Yeast – all products When a contact time of 1 minute and 5 minutes was used, a greater than 4 log reduction was observed for the 50, 80 and 100% solutions tested.	[redacted] (2016) (Report Nos: 4073-1, 4074-1, 4075-1, 4076 -1)
	Deosan Activate Pre/Post Conc. AG218 (MetaSPC1)				[redacted] (2016) (Report Nos: 4069-1, 4070-1, 4071-1, 40772-1)
	Deosan Activate Pre/Post AG217 (MetaSPC2)				[redacted] (2016) (Report Nos: 4058-1, 4059-1, 4060-1, 40761-1)
	Deosan Activate PVP Plus AG215 (MetaSPC2)				[redacted] (2016) (Report Nos: 4054-1, 4055-1, 4056-1, 40757-1)
	Deosan Activate Barrier AG216 (MetaSPC3)				[redacted] (2016) (Report Nos: 4062-1, 4063-1, 4064-1, 40765-1)
Disinfection of lactating animals' teats.	Deosan Activate Pre AG106 (MetaSPC1)	Bacteria (*S. aureus*) Yeast (*C. albicans*)	[redacted]	[redacted]	[redacted] (2016) (Report No: L16/0302.1)

Phase 2 Step 2 [redacted]	Deosan Activate Pre/Post Conc. AG218 (MetaSPC1)		[redacted]		[redacted] (2016) (Report No: L16/0301.1)
	Deosan Activate PVP Plus AG215 (MetaSPC2)				[redacted] (2016) (Report No: L16/0076.1)
	Deosan Activate Barrier AG216 (MetaSPC3)				[redacted] (2016) (Report No: L16/0077.1)

Conclusion on the efficacy of the product

The label claims for the product family are:

- Effective against and gram-negative bacteria, yeasts [redacted] being relevant for teat disinfection.

The UK CA considers that 'for teat disinfection' could imply efficacy against a range of organisms. The applicant has provided a specific label claim and data addressing the use of the product family against different groups of potentially relevant microorganism. The UK CA considers that the applicant should always ensure it is clearly stated which target organisms efficacy has been demonstrated against on the product label, e.g. for teat disinfection (kills bacteria, yeast [redacted] or equivalent wording).

It is typically not considered practical to have a pre-milking contact time in excess of 60 seconds or a post-milking contact time in excess of 5 minutes for teat disinfectants. The applicant has stated (and it is reflected in the instructions for the product family) that the minimum pre- milking contact time for the products is 15 seconds. For post-milking uses the applicant has not specified a minimum contact time but has provided the following statement:

'Products, which are provided for post-milking application, have no contact time indicated on their labels, as the actual contact time of the post-milking applied disinfectant in practice is longer than the 5 minutes contact time in the laboratory study. Thus, it can be concluded that a sufficient efficacy is ensured by following the use instructions on the labels.'

The UK CA considers this to be acceptable provided it is made clear that when used for post milking applications the products should not be wiped off after application to ensure the required contact time is achieved.

For all the meta-SPCs the intended use concentration of iodine is 0.3% available iodine. The applicant has stated that they consider that the defined variations specified for the meta-SPCs concerning the non-active substances, which are substances for pH adjustment, skin conditioners, thickeners and a surfactant, can be considered as non-critical for the biocidal efficacy.

In order to demonstrate that the variation in non-active components is not impacting upon the biocidal efficacy of the products within the family the applicant has provided efficacy tests on products within each of the meta-SPCs. For each of the meta-SPCs the following products were tested:

Concentrates – Deosan Activate Pre AG106 and Deosan Activate Pre/Post Conc.
Liquids –Deosan Activate Pre/Post AG217 and Deosan Activate PVP Plus AG215
Gels – Deosan Activate Barrier AG216

The concentrations of the co-formulates in the products tested vary. The products tested are generally representative of the ranges of concentrations of each co-formulate stated in the overall product family. The tests submitted show that the results for these products are comparable and the UK CA therefore considers that the products within the meta-SPC specification limits can be expected to have a similar biocidal efficacy.

The applicant has submitted phase 2 step 1 tests in support of the product families bactericidal (EN1656), yeasticidal (EN1657) [redacted]

[redacted] which all demonstrate the efficacy of the product family at or below the recommended in use concentration according to the pass criteria for the relevant standard protocol. The minimum contact time used in the tests against bacteria and yeast was 15 seconds. [redacted]

The applicant has also conducted testing following the protocol submitted to the efficacy working group by the iodine registration group.

Some of the phase 2 step 2 tests provided (shaded grey in the table above) are not considered to be valid. It is noted that the recovery rate of microorganisms from the control was not acceptable and decreasing log reductions were observed with increasing product concentrations in some of the tests. In light of the issues experienced the applicant repeated the testing and has provided valid data from both their in-house testing facilities and an external laboratory.

Due to the nature and novelty of applied phase 2 step 2 tests, still being under development during the dossier submission and not yet agreed by CEN WG2 as final protocol, a greater variation of results can be expected to occur more often. More consistent results were, however, obtained in further, improved studies carried out by PT3 IRG subgroup in 2015 (> 3 log reduction at 2000 ppm iodine use level). Thus, it is highly probable that the few results showing a < log 3 reduction at 80% use level are not caused by product deficiency, but are more due to a test design imperfection at the time the tests were carried out.

When the products were tested at their recommended in-use concentrations in the phase 2 step 2 tests a minimum of a 4 log reduction was observed for each target organism when tested with a contact time of 1 minute or more (except where experimental issues were noted). A minimum of a 3 log reduction in bacteria and a 4 log reduction in yeast was noted when a contact time of 30 seconds was tested.

The UK CA considers the level of soiling used in the laboratory tests performed to be sufficient to support the use of the product family.

The product family contains coformulants that have been identified as active substances but are not declared as active substances in the Deosan product family (see the Confidential Annex of this PAR (section 3.4.3)). The applicant has stated that they are added in small amounts [redacted] to the products and serve as pH-adjusters to keep the pH of the product in the range of 4.0-4.5.

The applicant has provided a statement to justify why these coformulants can be considered to be non-active in this product family (see the Confidential Annex of this PAR (section 3.4.3)).

The UK CA accepts the applicant's statement and considers that it is reasonable to consider these coformulants as non-active substances in this product family.

As a result of the evaluation of the physical, chemical and technical properties of the products in the product family it has been identified that after 24 months of storage there is a loss of active substance in excess of 10% (approximately 24% after 24 months) for the gel product Deosan Activate Barrier AG216. The applicant has provided the argument that after 24 months storage the efficacy studies 'have demonstrated, that bactericidal and yeasticidal efficacy was already achieved by 150-300 ppm iodine' and

that the observed reduction in active substance should be considered to be acceptable. The UK CA notes that these concentrations of active substance may not be fully supported by the phase 2 step 2 data submitted, but that the phase 2 step 2 data do demonstrate the efficacy of the product according to the agreed criteria for pre and post milking applications against bacteria and yeast when the product is tested at 80% of the recommended in use concentration. [redacted] he UK CA therefore considers that the efficacy of the product family has not been fully demonstrated following a greater than 20% reduction in active substance concentration. Based on the efficacy studies alone,a maximum shelf life of 18 months (corresponding to a 17.4% drop in active substance) is recommended for Deosan Activate Barrier AG216.

The UK CA considers the data submitted to be acceptable in support of the product families bactericidal and yeasticidal efficacy for pre and post milking applications.

[redacted]

According to the information provided above, the following conclusions can be drawn:

Conclusion

The UK CA considers that the efficacy of the products in the family is demonstrated for use at concentrations of 0.3-0.32 % with a minimum contact time of 30 seconds for pre-milking and 5 minutes for post-milking
Additionally, the following instruction should be included on the label '*The product must be brought to temperature >20°C before use.'*

The minimum contact time for pre-milking applications is 30 seconds [redacted] and for post-milking application is 5 minutes. To ensure sufficient contact time for post-milking application, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Based on the efficacy results, the label claims for the product family are:
- Effective against, yeasts [redacted] being relevant for teat disinfection.

[redacted]

Please note: following discussion at BPC-26, meeting of the Biocidal Products Committee (BPC), virucidal efficacy claims were not authorised. For further information please see the BPC opinion, which is available on the ECHA website.

2.2.5.6 Occurrence of resistance and resistance management

The applicant has stated that:

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

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

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

2.2.5.7 Known limitations

There are no known limitations and no undesirable or unintended side effects have been observed.

2.2.5.8 Evaluation of the label claims

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

- For teat disinfection* (*kills bacteria, yeast [redacted] pre-milking
- For teat disinfection* (*kills bacteria, yeast [redacted] post-milking
- Minimum contact time for use against bacteria and yeast 30 seconds
- [redacted]

Please note: following discussion at BPC-26, meeting of the Biocidal Products Committee (BPC), virucidal efficacy claims were not authorised. For further information please see the BPC opinion, which is available on the ECHA website.

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

Not relevant for this product family.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

This is a Union authorisation for a biocide product family (BPF). The family contains 23 products.

The products fall into the following types:
- AL (any other liquid)
- SL (soluble concentrate)
- GW (water soluble gel)

The product contains the active substance, iodine (0.3 – 1.6 %).

No new studies have been performed in support of the application. The classification is based on intrinsic properties of individual components of the biocidal products pertaining to the BPF as well as read-across to available studies performed with similar formulations (studies in the AR).

No classification is proposed for human health, as the criteria for classification under Regulation (EC) 1272/2008 are not met.

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. According to the CLP principles BPF does not need to be classified with respect to local effects on the skin. **Co-formulant 1, co-formulant 2 and co-formulant 3** For a discussion of the CLP principles relating to classification for skin corrosion/irritation due to the presence of three of the co-formulants in the product see the confidential annex (section 3.4.2 -Assessment of effects on Human Health, sub-section: 'Skin corrosion/irritation and eye irritation – co-formulant 1, co-formulant 2 and co-formulant 3').
Classification of the product according to CLP and DSD	No classification required.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Does not cause severe eye damage or eye irritation
Justification for the value/conclusion	Based on read-across to available studies performed with a similar mixture and on intrinsic properties of individual components of the biocidal products pertaining to the BPF.

	Co-formulants 1, 2 and 3 For a discussion of the CLP principles relating to classification due to the presence of three of the co-formulants in the product see the confidential annex (section 3.4.2 -Assessment of effects on Human Health, sub-section: 'Skin corrosion/irritation and eye irritation – co-formulant 1, co-formulant 2 and co-formulant 3'). According to the CLP principles, the BPF does not need to be classified with respect to local effects on the eye. **Co-formulant 4** According to the CLP principles, the maximum concentration of the **co-formulant 4** would trigger a classification of the BPF with respect to severe eye damage (Eye Dam. 1; H318). The applicant has referred to an eye irritation study, performed with a similar mixture containing **co-formulant 4** at a higher concentration, which demonstrated the absence of an eye irritating/eye damaging potential. Full details are given in the expert statement attached in section 13 of the IUCLID dossier (see document '09_CONFIDENTIAL_2015-07-03_Expert statement C&L_Diversey.pdf') For details of the of the formulation comparison carried out for eye irritation and the formulation details of the similar mixture containing co formulant 4, please see the Member State Confidential Annex (section 3.3.1 -Assessment of effects on Human Health, sub-section: 'Eye irritation – co-formulant 4').
Classification of the product according to CLP and DSD	No classification required.

Respiratory tract irritation

No information has been submitted to experimentally assess the potential for respiratory tract irritation as a result of inhalation exposure to the biocidal product. The SDSs for one co-formulant states that the substance "may cause respiratory irritation". However, this co-formulant is present at a low concentration (less than 2 %) in the product and is not known to the UK CA to be a respiratory sensitiser, and inhalation exposure of humans to these co-formulants will be negligable or very low due to the physical nature and usage of the product; thus, this co-formulant presents no realistic concern in relation to respiratory sensitisation to humans. The product does not meet the classification criteria for dermal or ocular irritation and it can be predicted that it will not have the capacity to cause respiratory tract irritation.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	The product is not a skin or eye irritant, and it can be predicted that the product is not a respiratory tract irritant. This conclusion is consistent with the available information on the irritant properties of the active ingredient and each of the co-formulants.
Classification of the product according to CLP and DSD	None proposed.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. According to the CLP principles, the individual products of the BPF, and thus the BPF itself, do not need to be classified with respect to skin sensitisation.
Classification of the product according to CLP and DSD	No classification required.

Respiratory sensitization (ADS)

The product has not been tested for respiratory sensitisation. Based on the hazard information on the active substance and other co-formulants, there are no known causes of respiratory sensitisation.

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No concerns regarding this endpoint
Justification for the value/conclusion	No hazard triggers from active substance or co-formulants
Classification of the product according to CLP and DSD	None proposed.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. According to the CLP principles, the BPF does not need to be classified with respect to acute oral toxicity.
Classification of the product according to CLP and DSD	No classification required.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. According to the CLP principles, the BPF does not need to be classified with respect to acute inhalation toxicity. Iodine is classified (harmonised) as Acute Tox Cat 4 (inhalation), H332 (no other co-formulants are so classified). There is no SCL. Iodine is present at a minimum of 0.3 % and a maximum of 1.6 %.
Classification of the product according to CLP and DSD	No classification required.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal products pertaining to the BPF. According to the CLP principles, the BPF does not need to be classified with respect to acute dermal toxicity. Iodine is classified (harmonised) as Acute Tox Cat 4 (dermal), H312 (no other co-formulants are so classified). There is no SCL. Iodine is present at a minimum of 0.3 % and a maximum of 1.6 %.
Classification of the product according to CLP and DSD	No classification required.

Information on dermal absorption

Dermal absorption: 12 % (applicable to the dilution and concentration)

The study in the AR was done with two biocide formulations (codes: "Io-Shield" = PE 305-1 and "Masodine" = BIOCIDE 1006). These were the "representative" formulations for approval of the active. Comparison of the tested formulations with the proposed formulation indicates that they are similar and the test results can therefore be used to support the proposed formulation. [redacted] Please see the Member State Confidential Annex for details of the UK CA formulation comparison.

The results demonstrate that in the concentration range tested (0.26 % to 0.66 %), the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations. It is therefore appropriate to use a dermal absorption of 12 % for the concentrate and dilution.

Data access:

The LoA indicates that the applicant has access to all data included in the iodine dossier.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Iodine
Value(s)*	12 %
Justification for the selected value(s)	It was demonstrated that regardless of iodophor type (i.e. alcohol ethoxylate-complexed iodine or PVP-iodine) and concentration of co-formulants, the dermal absorption of total iodine was ca. 12% when evaluated according to the most recent EFSA guidance on dermal absorption (EFSA Journal 2012;10(4):2665). From the final CAR (Iodine PT-3 2013, SE), it is stated that: *"The results further demonstrated that in the concentration range tested, the dermal penetration of total iodine was independent of the concentration of iodine in the biocidal formulations."* Please note that the value of 12% agreed in the CAR is considered applicable by UK CA for PT-3 water-based formulations containing iodine within a range of 0.26 – 0.66 % iodine (assessed in CAR). PT-3 formulations containing higher / lower concentrations of the active substance iodine and surfactants will therefore be considered on a case-to-case basis according to the information provided by the applicant and available in the CAR. In this case the product is not a skin or eye irritant / corrosive and does not contain any skin sensitizing substances and is, therefore, not expected to exert effects on the skin that might modify the absorption characteristics of iodine. The UK CA's conclusion is therefore that it is conservative to use a dermal absorption value of 12% agreed during the evaluation of iodine (PT-3) for all the Meta SPCs in this biocidal product family (Iodine concentration 0.3 – 1.6 % w/w available iodine).

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

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

No substances of concern that require evaluation have been identified. No classification of the product is required for human health.

Available toxicological data relating to a mixture

Not relevant to this authorisation.

Other

Not relevant to this authorisation.

2.2.6.2 Exposure assessment

The products in the Deosan Activate family are used for the disinfection of cow teats pre- and/or post- milking of cows or other milkable animals. Products are supplied as soluble concentrates (Meta SPC 1), ready-to-use liquids (Meta-SPC 2) or ready-to-use gel (Meta-SPC 3). For Meta-SPC 1 & Meta SPC 2 application is through spraying, dipping or foaming. For Meta SPC 3, application is through dipping only. Soluble concentrates (Meta-SPC 1) must be diluted with water prior to application. When applied pre- milking, the product is wiped off the teats after the required contact time, before attaching the teats to the milking unit. When the product is applied after milking, the applied product is left to dry on the teat skin.

For human health, both iodine and sodium iodide are considered relevant to the exposure assessment. For the calculation of total iodine, the UK CA has taken into account that sodium iodine contains 84.55% iodine.

Farmers are likely to apply the product themselves and are considered to be professional users for this type of product i.e. they are used to handling these product types regularly, they have access to relevant safety information and they can be expected to wear personal protective equipment (PPE) when handling the products. For the purposes of the human health exposure assessment, manual application both pre- and post-milking, and pre- or post- milking only has been considered.

The exposure assessment was carried out on the basis that an individual farmer will not be present for more than 2 milkings/day in line with the harmonised value given in HEAdhoc rec. no. 13. There may be some farms that carry out 3 milkings / day leading to a maximum of 3 applications/ day when the products are applied pre- or post- milking or 6 applications /day when the products are applied pre and post milking however, as an individual farmer is not expected to be present for all 3 milkings, this will have no impact on the human exposure assessment.

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

Summary table: relevant paths of human exposure		
Exposure	**Primary (direct) exposure**	**Secondary (indirect) exposure**

path	Industrial use	Professional use	Non-professional use	Industrial use	Professional use	General public	Via food
Inhalation	n.a.	yes	n.a.	n.a.	no	no	no
Dermal	n.a.	yes	n.a.	n.a.	no	no	no
Oral	n.a.	no	n.a.	n.a.	no	no	yes

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

INTENDED USES

Overview of applications and application rates for the Deosan Activate product family

Application	Maximum application rate of the in-use dilution	Maximum concentration of the in-use dilution
Dip application	10 mL/cow/treatment (liquid or foam)	0.44 % w/w total iodine
Spray application	15 mL/cow/treatment	0.44 % w/w total iodine

List of scenarios

Primary and secondary exposure scenarios pertaining to the proposed use of the product are detailed in the table below.

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)
1.	Mixing/loading	Primary exposure –mixing/loading of the concentrated product (Meta-SPC 1)	Professionals
2.	Decanting	Primary exposure – decanting of the ready-to-use product (Meta-SPC 2 & 3)	Professionals
3.	Application through spraying	Primary exposure – cow teat disinfection through manual spraying using a trigger sprayer or electronic sprayer (Meta SPC 1 & 2)	Professionals
4.	Manual application through the use of dipping cups	Primary exposure – cow teat disinfection through the use of dipping cups (Meta SPC 1, 2 & 3)	Professionals
5.	Drying of teats	Primary exposure – removal of the freshly applied product before attachment of the milk clusters (Meta SPC 1, 2 & 3)	Professionals
6.	Cleaning of equipment	Primary exposure – cleaning of manual/semi-automatic equipment after use (Meta SPC 1, 2 & 3)	Professionals
7.	Connecting transfer lines	Primary exposure – loading of the ready-to-use product into semi-automated dipping and automated spraying system (Meta-SPC 2 & 3). For this task, the professional user loads the RTU products via connecting transfer lines.	Professionals
8.	Application through automatic spraying	Primary exposure – cow teat disinfection through an automatic spraying method. As the process is automated, exposure during application is not expected.	Professionals
9.	Application through semi-automatic dipping	Primary exposure – cow teat disinfection through a semi-automatic dipping method	Professionals

Industrial exposure

The Deosan Activate product family is not intended for use by industrial users.

Professional exposure

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

Whilst elemental iodine has a high vapour pressure of 40.7 Pa at 20ºC, the iodine CAR informs us that evaporation of iodine from water based products is assumed to be very low: "Iodine is supposed to react immediately with organic matter (microorganisms, protein substances etc.), also by formation of different iodine species (iodide etc.). For these reasons and in respect of the natural background values in the air, iodine evaporation and – consequently - contamination of the air is regarded as negligible". In addition the applicant has provided additional information outlining why no evaporation is expected (please see annex 3.2, figure 1.1. for details). Based on this, evaporation of iodine is not expected and inhalation exposure to volatilised iodine has not been considered.

Scenario 1 – Mixing/loading products supplied as a concentrate (meta-SPC 1)

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

Description of Scenario 1		
Professional users mixing/loading a concentrated product (Meta SPC 1). *Potential exposures are via the dermal route.*		
	Parameters	Value
Tier 1	Maximum concentration of iodine in the concentrate	2.19% w/w
	Adult bodyweight	60 kg
	Dermal penetration of iodine	12%
	Indicative potential hand exposure value for pouring from a 1 litre container (75th percentile)	0.01 ml
Tier 2	PPE: protective gloves	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

Mixing and loading model 4 provides indicative hand exposure values of 0.01 ml/treatment for 1 L containers, 0.2 ml/treatment for 5 L containers and 0.5 ml/treatment for 10 & 20 L containers. The guidance recommends that the indicative value should be used in line with the total amount of required solution/day. The applicant has given a maximum application rate of 15 ml of in-use solution/cow/treatment. As the products can be applied both pre- and post- milking to a herd of 82 cows (default assumption), the total amount of in-use solution applied per day can be calculated as 15 ml x 4 x 82 = 4.92 litres. The lowest ratio for dilution is 1 part product to 4 parts water therefore the amount of concentrated product handled by user will always be < 1 litre and as such the indicative exposure value of 0.01 ml is most appropriate.

The highest amount of iodine in the concentrated products is 2.19% w/w iodine. Systemic exposure to iodine during mixing/loading of concentrates can be calculated as follows (assuming a default adult bodyweight of 60 kg and a dermal absorption value of 12%):

- 0.01 ml x 2.19% w/w iodine x 12% / 60 kg = 4.38×10^{-4} mg/kg bw/day*

*assuming a product density of 1g/ml

Tier 2 assessment

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

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

Calculations for Scenario 1

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s. /day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1	1 (no PPE)	Negligible	0.0263	n.a.	0.0004
Scenario 1	2 (gloves)	Negligible	0.0026	n.a.	0.00004

Scenario 2 – Decanting ready-to-use products (meta-SPC 2 & meta SPC 3)

HEAdhoc recommendation no.13 (agreed at the Human Heath WGI, 2017) informs us that Mixing and loading model 4 should be used to estimate dermal exposure for a professional user decanting ready-to-use products into spraying, dipping or foaming equipment.

Description of Scenario 2

Professional users decanting a ready-to-use product (meta SPC 2 & meta-SPC 3). *Potential exposures are via the dermal route.*		
	Parameters	Value
Tier 1	Maximum concentration of iodine	0.44% w/w
	Adult bodyweight	60 kg
	Dermal penetration of iodine	12%
	Indicative potential hand exposure value for pouring from a 5 L container (75th percentile)	0.2 ml
Tier 2	PPE: protective gloves	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no personal protective equipment is worn.

A total of 4.92 litres of solution is required per day (please refer to scenario 1 for details of this calculation). As such, the indicative value of 0.2 ml (applicable to pouring from a 5 L container) from Mixing and loading model 4 is most appropriate. The highest concentration of iodine in the ready-to-use products is 0.44% w/w iodine. Systemic exposure to iodine during decanting can be calculated as follows (assuming a default adult bodyweight of 60 kg and a dermal absorption value of 12%):

- 0.2 ml x 0.44% w/w iodine x 12% / 60 kg = 1.76 x 10^{-3} mg/kg bw/day*

*assuming a product density of 1g/ml

Tier 2 assessment

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

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

In considering the frequency of exposure to professional users, the long-term AEL 0.01 mg/kg bw/day is considered the most relevant endpoint.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s. /day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 2	1 (no PPE)	Negligible	0.1056	n.a.	0.0018

Scenario 2	2 (gloves)	Negligible	0.0106	n.a.	0.0002

Scenario 3 – Application of the products to cow teats through manual spraying

The applicant informs us that the Deosan Activate biocidal product family may be applied to cow teats through manual spraying. The use of disposable plastic gloves by the milking staff is likely for both hygiene reasons and to avoid cross contamination.

HEAdhoc recommendation no. 13 (2017) informs us that dermal exposure during the application of the products through manual trigger spraying or electronic spraying should be assessed using Consumer product spraying and dusting model 2. The recommendation suggests an exposure duration of 55 minutes when application occurs both pre- and post- milking (assuming a spray duration of 10 seconds/cow/treatment, a herd size of 82 cows and an assumption that cows are milked twice per day).

Description of Scenario 3		
An adult disinfects cow teats (both pre- and post- milking) using a manual trigger sprayer or electronic sprayer at an in-use concentration of 0.44 % w/w iodine. *Potential exposure is via the dermal route.*		
Tier	Parameters	Value
	Maximum in-use concentration of iodine	0.44 % w/w
	Adult bodyweight	60 kg
	Adult inhalation rate	1.25 m^3/hour
	Dermal penetration of iodine	12 %
	Exposure duration (pre- and post- milking)	55 minutes
	Exposure duration (pre- or post- milking)	27.5 minutes
	Hand and forearm indicative exposure value (75^{th} percentile)(no PPE)	36.1 mg/minute
	Legs, feet and face indicative exposure value (75^{th} percentile)(no PPE)	9.7 mg/minute
	Inhalation indicative exposure value	10.5 mg/m^3
2	PPE: protective gloves	90% protection (10% penetration)
3	PPE: coated coveralls and boots	90% protection (10% penetration)

Tier 1 assessment

It is assumed that no protective equipment is worn.

Tier 2 assessment

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

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

Tier 3 assessment

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

- The protection afforded by coated coveralls. HEEG opinion 9 (2010) informs us that suitable protective coveralls will provide 90% protection. As the indicative exposure value includes exposure to the legs and feet, chemical resistant boots are also required.

In considering the frequency of exposure to professional users, the long-term AEL of 0.01 mg/kg bw/day is considered the most relevant endpoint.

Calculations for Scenario 3

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
3 (pre- and post-milking)	1 (no PPE)	0.0529	1.3300	n.a.	0.0230
	2 (gloves)	0.0529	0.3865	n.a.	0.0073
	3 (gloves, coated coveralls & boots)	0.0529	0.1330	n.a.	0.0031
3 (pre- or post-milking only)	1 (no PPE)	0.0265	0.6650	n.a.	0.0115
	2 (gloves)	0.0265	0.1933	n.a.	0.0037
Detailed calculations can be found in Annex 3.2, Tables 1.2 – 1.6					

Local effects

Iodine has an OEL (occupational exposure limit) of 1 mg/m^3. Based on the indicative inhalation value of 10.5 mg/m^3 provided in consumer product spraying and dusting model 2, and considering that the in-use solution contains 0.44% w/w iodine, the maximum air concentration of iodine is calculated to be 0.0462 mg/m^3 of iodine. This value is below the OEL and the risk from local effects is therefore acceptable.

Scenario 4 – Cow teat disinfection through the use of manual dipping cups (liquid or foam)

HEAdhoc recommendation no. 13 (agreed at the 2017 human health WG) informs us that exposure during the use of dipping cups is covered by the exposure estimate for a user mixing and loading/decanting the product (please refer to scenario 1 & 2 above). Furthermore, it is assumed that dipping cups are designed specifically for this task. This cup has an upper compartment for application of the dip and a lower compartment as reservoir for the dipping solution. During the application the worker holds the cup at the lower compartment, so direct hand exposure to the biocide product or a treated teat is avoided. As such, no further consideration of cow teat disinfection through dipping is required. Of note, it was agreed at HEAdhoc-1-2016 meeting that application of a biocidal product in the form of foam by dipping cups is covered by the application of liquid by dipping cups.

Scenario 5 – Removal of freshly applied product pre-milking

The SPC document for the Deosan Activate product family informs the user to "prepare teats before milking, apply product to the full length of each teat. Leave in contact with the skin for at least 15 seconds. Thoroughly remove the product using a single service paper towel/cloth leaving the teats clean and dry". As such, consideration of exposure during the removal of freshly applied product pre-milking is required. The highest in-use concentration is 0.44 % w/w iodine.

Description of Scenario 5		
A professional user wiping cow teats with a dry paper towel after application of the product (prior to fitting the milking cluster). *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	In-use concentration of total iodine (pre-milking)	0.44 % w/w
	Adult bodyweight	60 kg
	Surface area of cow teat	44 cm^2
	Thickness of liquid layer on teat	0.01 cm
	Dermal penetration	12 %
Tier 2	Protection afforded by gloves	90 % protection (10 % penetration)

Tier 1 assessment

It is assumed that no protective equipment is worn.

HEAdhoc recommendation no. 13 (2017) informs us that hand exposure can be calculated as 0.1% of the amount of biocidal product on the surface area. The surface area corresponds to the teats of a herd of dairy cows and the guidance informs us the surface area of a teat is 44 cm^2. To calculate the amount of the biocidal product on the surface area, the layer thickness approach is considered appropriate; HEEG opinion 16

informs us that the estimated thickness of the liquid layer on the skin is 0.01 cm. The total amount of biocidal product on a herd of cows can therefore be calculated as 44 cm^2/teat x 4 teats x 0.01 cm x 82 cows = 144.32 cm^3 = 144.32 g of in-use solution (assuming a density of 1g/cm^3).

Assuming there are two pre-milking applications/day, hands are exposed to 0.1% of the amount of product on cow teats for each application and the highest in-use dilution for pre-milking is 0.44% w/w, the external dose on hands during removal of freshly applied product pre-milking can be calculated as 144.32 g x 2 x 0.1% x 0.44% = 1.27 x 10^{-3} g iodine/day = 1.2700 mg iodine/day

The systemic dose is then calculated taking into account a dermal absorption value of 12% and an adult bodyweight of 60 kg (i.e. 1.2700 x 12% / 60 kg = 0.0025 mg/kg bw/day).

Tier 2 assessment

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

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

In considering the frequency of exposure to professional users, the long-term AEL of 0.01 mg/kg bw/day is considered the most relevant endpoint.

Calculations for Scenario 5

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
5	1 (no PPE)	Negligible	0.1524	n.a.	0.0025
5	2 (gloves)	Negligible	0.0152	n.a.	0.0003

Scenario 6 – Cleaning of equipment

HEAdhoc Recommendation no. 13 (2017) proposes that the indicative value of the RISKOFDERM 'loading liquid, automated or semi-automated' for the cleaning phase of different equipment (dipping cup, spraying nozzle etc.) of 0.92 mg/min is most appropriate to assess the cleaning of equipment. The guidance also suggests an exposure duration of 5 minutes. Any product left in the equipment is likely to be highly diluted during cleaning however, using a precautionary approach, it is assumed the cleaning water contains 0.44% w/w iodine (i.e. it is assumed there is no further dilution of the in-use product with cleaning water).

Description of Scenario 6

A professional user cleaning treatment equipment after application of the Deosan Activate product family. *Potential exposure is via the dermal route.*		
	Parameters	Value
Tier 1	Maximum in-use concentration of total iodine	0.44 % w/w
	Adult bodyweight	60 kg
	Indicative exposure value	0.92 mg/min
	Task duration	5 minutes
	Dermal penetration	12 %
Tier 2	Protection afforded by gloves	90 % protection (10 % penetration)

Tier 1 assessment

It is assumed that no protective equipment is worn.

Based on the assumption that a user cleaning equipment is exposed 4.6 mg product/day (i.e. 0.92 mg x 5 minutes) and assuming that the product contains 0.44% w/w iodine, systemic exposure can be calculated as follows (based on a default adult bodyweight of 60 kg and a dermal absorption value of 12%):

4.6 mg x 0.44% x 12% / 60 kg = 0.00004 mg iodine/day

Tier 2 assessment

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

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

In considering the frequency of exposure to professional users, the long-term AEL of 0.01 mg/kg bw/day is considered the most relevant endpoint.

Calculations for Scenario 6

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
6	1 (no PPE)	negligible	0.0024	n.a.	0.00004
6	2 (gloves)	negligible	0.0002	n.a.	0.000004

Scenario 7 – Connecting of transfer lines

Ready-to-use products (meta-SPC 2 & 3) may be loaded into semi-automated dipping and automated spraying systems via transfer lines. Exposure during connecting transfer lines is considerably lower than during manual loading and this scenario is thus considered covered by scenario 2.

Scenario 8 – Application through automatic spraying (post-milking only)

As the process is automated, exposure during application is not expected.

Scenario 9 – Application of the products to cow teats through semi-automated dipping (post-milking only)

Semi-automated dipping is covered by manual dipping, Please see scenario 4 for details.

Combined scenarios

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

Summary table: combined systemic exposure from professional uses for pre-milking only					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 1, 3, 5 & 6; mixing/loading the concentrate, spray application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0265	0.8461	n.a.	0.0145
	Tier 2 (gloves)	0.0265	0.2114	n.a.	0.0040
Meta SPC 1 1, 4, 5 & 6; mixing/loading the concentrate, dip application, removal of product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1811	n.a.	0.0030
	Tier 2 (gloves)	negligible	0.0181	n.a.	0.0003

Meta SPC 2 2, 3, 5 & 6; decanting (RTU), spray application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0265	0.9250	n.a.	0.0159
	Tier 2 (gloves)	0.0265	0.2193	n.a.	0.0041
Meta SPC 2 & 3 2, 4, 5 & 6; decanting (RTU), dip application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.2604	n.a.	0.0043
	Tier 2 (gloves)	negligible	0.0260	n.a.	0.0004

Summary table: combined systemic exposure from professional uses for post-milking only					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 1, 3 & 6; mixing/loading the concentrate, spray application and post-application cleaning of equipment	Tier 1 (no PPE)	0.0265	0.6937	n.a.	0.0120
	Tier 2 (gloves)	0.0265	0.1962	n.a.	0.0037
Meta SPC 1 1, 4 & 6; mixing/loading the concentrate, dip application and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.0287	n.a.	0.0005
	Tier 2 (gloves)	negligible	0.0260	n.a.	0.00005
Meta SPC 2 2, 3 & 6; decanting (RTU),	Tier 1 (no PPE)	0.0265	0.7730	n.a.	0.0133

spray application and post-application cleaning of equipment	Tier 2 (gloves)	0.0265	0.2041	n.a.	0.0038
Meta SPC 2 & 3 2, 4 & 6; decanting (RTU), dip application and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1080	n.a.	0.0018
	Tier 2 (gloves)	negligible	0.0108	n.a.	0.0002

Summary table: combined systemic exposure from professional uses for pre- and post-milking					
Scenarios combined		**Estimated inhalation uptake** (mg a.s./day)	**Estimated dermal uptake** (mg a.s./day)	**Estimated oral uptake** (mg a.s./day)	**Estimated total uptake** (mg a.s./kg bw/day)
Meta-SPC 1 1, 3, 5 & 6; mixing/loading the concentrate, spray application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0529	1.511	n.a.	0.0261
	Tier 2 (gloves)	0.0529	0.4046	n.a.	0.0076
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0529	0.1511	n.a.	0.0034
Meta SPC 1 1, 4, 5 & 6; mixing/loading the concentrate, dip application, removal of product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.1811	n.a.	0.0030
	Tier 2 (gloves)	negligible	0.0181	n.a.	0.0003

Meta SPC 2 2, 3, 5 & 6; decanting (RTU), spray application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	0.0529	1.5904	n.a.	0.0274
	Tier 2 (gloves)	0.0529	0.4125	n.a.	0.0078
	Tier 3 (gloves, coveralls & boots for spraying, gloves for other activities)	0.0529	0.1590	n.a.	0.0035
Meta SPC 2 & 3 2, 4, 5 & 6; decanting (RTU), dip application, removal of the product pre-milking and post-application cleaning of equipment	Tier 1 (no PPE)	negligible	0.2604	n.a.	0.0043
	Tier 2 (gloves)	negligible	0.0260	n.a.	0.0004

Exposure of the general public

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

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

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

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier (PPE)**	**Estimated total uptake** (mg a.s./kg bw/day)
Scenario 1:	Professionals	1 (no PPE)	0.0004

mixing/loading		2 (gloves)	0.00004
Scenario 2: decanting	Professionals	1 (no PPE)	0.0018
		2 (gloves)	0.0002
Scenario 3: manual spraying (pre- and post-milking)	Professionals	1 (no PPE)	0.0230
		2 (gloves)	0.0073
		3 (gloves, coated coveralls & boots)	0.0031
Scenario 3: manual spraying (pre- or post-milking)	Professionals	1 (no PPE)	0.0115
		2 (gloves)	0.0037
Scenario 4: application via dipping cups	Professionals	Covered by scenarios 1 & 2	
Scenario 5: drying of teats	Professionals	1 (no PPE)	0.0025
		2 (gloves)	0.0003
Scenario 6: cleaning of equipment	Professionals	1 (no PPE)	0.00004
		2 (gloves)	0.000004
Scenario 7: transfer of product via connecting lines	Professionals	Covered by scenario 2	
Scenario 8: automated spraying	Professionals	No exposure expected	
Scenario 9: semi-automated dipping	Professionals	Covered by scenario 4	

Risk for consumers via residues in food

Introduction

In place of trials data to determine residues of iodine in milk following use of the products within Deosan Activate BPF, the applicant (Diversey Europe Operations B.V.) has provided a case in the form of a discussion paper "*Iodine residues in milk due to iodine-based teat-disinfection: Assessment of consumer safety*" (SCC, 29 June 2015), sponsored by the Iodine Registration Group (IRG) of which the applicant is a member. However it should be noted that the approach described in this discussion paper has not entirely been followed, instead decisions made in the human health working groups meeting and WebEx meetings have been implemented.

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

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

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

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

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

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

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

A more recent study (O'Brien, 2013) [REF 1] has been published where the effect of milk iodine concentrations after application of a teat-spray containing 0.5 % iodine and applied post- or pre- and post-milking were investigated. Another objective of this study was to quantify combined effects of teat disinfection and dietary supplementation of

iodine. Feed fortification levels tested were 30 mg and 70 mg per cow per day. In this evaluation, only the results of the teat disinfection without considering the influence of iodine supplementation by feed are presented. The results of the study have been presented in Table 1, and have been extrapolated to match the 'Deosan Active BPF' in-use conditions in Table 2. These residue levels reported for a manual spraying scenario are considered to represent the worst-case in terms of current application types (i.e. dipping, spraying or foaming) and level of automation (manual, semi-automatic or automatic/robotic milking).

Milking by robots is considered to be performed on average three times per day, and manual milking two times per day. At the Secure WebEx meeting (3-10-2017) it was concluded that '*the expected iodine residues in milk from two milking events per day for manual milking and from three events per day for automatic milking are considered comparable*'. Looking at the applied volume of product, on a daily basis there is little difference between automatic and manual milking. Therefore for the exposure calculations, data from 2x manual application in the O'Brien 2013 study is considered appropriate to support the robotic milking uses in the Deosan Activate BPF.

There may be some farms that carry out 3 milkings/ day leading to a maximum of 3 applications/ day when the products are applied pre- or post- milking and 6 applications/ day when the products are applied pre- and post- milking. However, as this is not considered common practice, and only a very small number of farms may carry out 3 milkings per day, this is not likely to influence the chronic risk assessment and has therefore not been assessed. The assessment has been completed using a realistic assumed application frequency of 2x pre- and post- milking applications/ day.

All products within the BPF have the same in-use concentration of iodine (0.30 %) and sodium iodide (0.13 %), with the maximum in-use concentrations based on formulation composition limits defined for all products as 0.32% iodine and 0.14% sodium iodide. Even though it is noted that both iodine forms are equally relevant for dietary exposure (total iodine), as the O'Brien study was based on 0.5 % available iodine the maximum available iodine content has been considered in the dietary risk assessment (0.32 %).

For the control group in "*Iodine concentrations in milk*" [REF 1], in which cows were treated with non-iodine teat disinfectant and 0 mg iodine/day feed supplementation, a 'baseline' of 217 µg/kg iodine in milk was established. This is equivalent to 224 µg/L based on the density of whole milk (1030 g/L), [REF 5]. This value can be considered to be in broad agreement with the mean value of 311 µg/L iodine in milk (range = 80 to 930 µg/L) reported in the 2000 UK MAFF Survey [REF 8], assuming that the additional iodine content may be accounted for by the use of iodine-based teat disinfectants and feed supplementation. It is noted that values reported by EFSA in monitoring studies conducted within the EU indicate mean levels of iodine in milk of 100 - 200 µg/L [REFs 2 and 3]. The most appropriate background level to use in the risk assessment was discussed and agreed in the Secure WebEx meeting (3-10-2017), where it was concluded that: '*General support was given to the derivation of an EU harmonised value. The value of 200 µg/L iodine in milk was considered appropriate as an EU harmonised value, based on the monitoring data from EFSA 2013 (EFSA Journal 2013;11(2):3101) and the O'Brien study.*'

Based on the assumed linear relationship between iodine concentration and iodine residues in milk, and the agreed background levels in milk of 200 µg/L, the estimated residues of iodine in milk have been derived and presented in Table 2. The average milk

yield in O'Brien, 2013 was reported as 21.6 kg/cow/day, which is in line with the value of 20 L/day as stated in the draft proposal for teat treatment scenarios. Therefore no further considerations to milk yields are considered within this evaluation.

Table 2 - Estimated residues of iodine in milk based on extrapolation of O'Brien 2013 data

Product	Iodine (%)	Applications	Estimated mean residues of iodine in milk (µg/L)	
			Proposed teat treatment	TOTAL milk (+ 200)
O'Brien 2013	0.500	[redacted]	[redacted]	[redacted]
O'Brien 2013	0.500	[redacted]	[redacted]	[redacted]
O'Brien 2013	0.500	[redacted]	[redacted]	[redacted]
Deosan Activate BPF	0.32	[redacted]	[redacted]	[redacted]
Deosan Activate BPF	0.32	[redacted]	[redacted]	[redacted]
Deosan Activate BPF	0.32	[redacted]	[redacted]	[redacted]

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

Example calculation for 2x post-milking:

[redacted]

Intake values (milk consumption) for dietary risk assessment

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

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

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

The EFSA Comprehensive European Food Consumption Database states an intake value of **1.05 L milk/day** for toddlers, the value referenced in the EFSA *"Scientific Opinion on*

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

The EFSA PRIMo v2 consumption model contains consumption data provided by several member states covering both acute and chronic risk assessments. This model is routinely used to make regulatory decisions for plant protection products under Regulation (EC) No. 1107/2009 and Regulation (EC) No. 396/2005. These decisions include the consumer risk assessments for the approval/renewal of active substances and for setting MRLs. Table 3 presents the mean chronic intake values for milk from this model.

Table 3 – Mean chronic intakes for milk from the EFSA PRIMo v2 model

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

† Taken from [REF 7]

‡ Density of whole milk 1030 g/L [REF 5]

As a chronic risk assessment (see section 'Toxicological reference values for iodine') is being undertaken only the intake values from the EFSA PRIMo v2 consumption model (**0.45 L adult and 0.46 L toddler**) have been used to estimate the dietary exposure of adults and toddlers to iodine. These values have been agreed at HH WG IV 2017. The estimated dietary exposure results are presented in Table 5.

Toxicological reference values for iodine

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

Table 4 - Upper Intake Levels (UL) for iodine established by the EU SCF

Population sub-group	UL (µg/day)
Children, 1-3 years	200
Children, 4-6 years	250

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

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

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

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

Additional considerations

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

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

2017 (March 2017) that the impact of pasteurisation on iodine levels in milk could not be concluded based on the current information and therefore the refinement not applied at this time.

Exposure assessments

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

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

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

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

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

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

The estimated dietary intakes of iodine have been compared to the relevant UL for adults (600 µg/day) and infants (200 µg/day) in Table 5. Intakes which exceed the respective UL are highlighted in red text.

Table 5 - Comparison of estimated daily iodine intakes of adults and infants to the relevant UL

	Adults (0.45 L)	Infants (0.46 L)
	Estimated daily intake (µg/day) [% of UL]	Estimated daily intake (µg/day) [% of UL]
2x pre-milking applications (0.32 % iodine)		
Intakes from proposed teat treatment	62 [10.3 % UL]	63 [31.6 % UL]
Total milk intake†	152 [25.3 % UL]	155 [77.6 % UL]
Total dietary intake‡	337 [56.2 % UL]	251 [125.6 % UL]
2x post-milking applications (0.32 % iodine)		
Intakes from proposed teat treatment	72 [12.0 % UL]	74 [36.9 % UL]
Total milk intake†	162 [27.0 % UL]	166 [82.9 % UL]
Total dietary intake‡	347 [57.9 % UL]	262 [130.9 % UL]
2x pre- and 2x post-milking (0.32 % iodine)		
Intakes from proposed teat treatment	134 [22.4 % UL]	137 [68.6 % UL]
Total milk intake†	224 [37.4 % UL]	229 [114.6 % UL]
Total dietary intake‡	409 [68.2 % UL]	325 [162.6 % UL]

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

Example calculation for 2x pre-milking applications for adults:

Data taken from Table 2: From teat treatment: 138 µg/L, background milk: 200 µg/L, total milk = 338 µg/L.
Iodine from other sources = 185 µg/day.

Iodine intake from teat treatment = 138 µg/L x 0.45 L = 62 µg/day
Percentage UL = (62/600) x 100 = 10.3 %

Total iodine from milk intake = 338 µg/L x 0.45 L = 152 µg/day
Percentage UL = (152/600) x 100 = 25.3 %

Total dietary intake = 152 µg/day + 185 µg/day = 337 µg/day
Percentage UL = (337/600) x 100 = 56.2 %

References

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

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

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

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

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

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

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

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

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

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	AEL long-term is applicable to all time frames – see below.				
AELmedium-term	AEL long-term is applicable to all time frames – see below.				
AELlong-term	EU Scientific Committee on Food (SCF, 2002) [(1)].	See footnote [(1)]	See footnote [(1)]	See footnote [(1)]	Adult-0.6 mg/day (0.01 mg/kg bw/d) Toddler- 0.2 mg/d
AEL inhalation	See AR.	See AR.	See AR.	See AR.	1 mg/m^3
ARfD	Not applicable. Substance is not toxic or harmful.				
ADI	Not applicable. Substance is not toxic or harmful.				

[(1)]: The SCF (2002) established an Upper Intake Level (UL) of 600 µg/day for adults and 200-450 µg/day for children and school pupils. The UL is equal to the AEL.
These values are as given in the AR for iodine.

Risk for industrial users

The Deosan Activate product family is not intended for use by industrial users.

Risk for professional users

Systemic effects

Task/ Scenario	Tier (PPE)	AEL mg/kg bw/d	Estimated uptake mg a.s./kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1- mixing/loading of the concentrate (Meta-SPC 1)	1 (no PPE)	0.01	0.0004	4%	yes
	2 (gloves)	0.01	0.00004	<1%	yes
Scenario 2 – decanting of RTU product (Meta-SPC 2 & 3)	1 (no PPE)	0.01	0.0018	18%	yes
	2 (gloves)	0.01	0.0002	2%	yes
Scenario 3 – application through spraying pre- and post- milking (Meta-SPC 1 & 2)	1 (no PPE)	0.01	0.0230	230%	no
	2 (gloves)	0.01	0.0073	73%	yes
	(gloves, coated coveralls & boots)	0.01	0.0031	31%	yes
Scenario 3 – application through spraying pre- or post- milking (Meta SPC 1 & 2)	1 (no PPE)	0.01	0.0115	115%	no
	2 (gloves)	0.01	0.0037	37%	yes
Scenario 4 – application through the use of dipping cups (Meta-SPC 1, 2 & 3)	Covered by scenarios 1 / 2				
Scenario 5 – removal of freshly applied product (pre-milking) (Meta-SPC 1, 2 & 3)	1 (no PPE)	0.01	0.0025	25%	yes
	2 (gloves)	0.01	0.0003	3%	yes
Scenario 6 – cleaning of equipment (Meta-SPC 1, 2 & 3)	1 (no PPE)	0.01	0.00004	<1%	yes
	2 (gloves)		0.000004	<1%	yes
Scenario 7- loading the RTU product via connecting of transfer lines (Meta SPC 1, 2 & 3)	Covered by scenario 2				

Scenario 8 – automatic spraying (Meta SPC 1 & 2)	No exposure expected
Scenario 9 – application through semi-automatic dipping (Meta SPC 1, 2 & 3)	Covered by scenario 4

Combined scenarios from primary exposure (2 milking events per day, pre-milking)

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 1, 3, 5 & 6 (mixing/loading, application through spraying pre-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0145	145%	no
	2 (gloves)		0.0040	40%	yes
Meta SPC 1 1, 4, 5 & 6 (mixing/loading, application through dipping pre-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0030	30%	yes
	2 (gloves)		0.0003	3%	yes
Meta SPC 2 & 3 2, 3, 5 & 6 (decanting, application through spraying pre-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0159	159%	no
	2 (gloves)		0.0041	41%	yes
Meta SPC 2 & 3 2, 4, 5 & 6 (decanting, application through dipping pre-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0043	43%	yes
	2 (gloves)		0.0004	4%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, pre-milking)

Residue values for pre-milking disinfection, as derived in Table 5 of the section "Risk for consumers via residues in food" below, have been added to the estimated professional user exposure.

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

Meta SPC 1 1, 3, 5, 6 (mixing/loading, application through spraying pre-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre-milking)	1 (no PPE)	0.01	0.0202	202%	no
	2 (gloves)		0.0096	96%	yes
Meta-SPC 1 1, 4, 5 & 6 (mixing/loading, application through dipping pre-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre-milking)	1 (no PPE)	0.01	0.0086	86%	yes
	2 (gloves)		0.0059	59%	yes
Meta-SPC 2 & 3 2, 3, 5 & 6 (decanting, application through spraying pre-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre-milking)	1 (no PPE)	0.01	0.0215	215%	no
	2 (gloves)		0.0097	97%	yes
Meta-SPC 2 & 3 2, 4, 5 & 6 (decanting, application through dipping pre-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre-milking)	1 (no PPE)	0.01	0.0100	100%	yes
	2 (gloves)		0.0061	61%	yes

Combined scenarios from primary exposure (2 milking events per day, post-milking)

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Meta SPC 1 1, 3 & 6 (mixing/loading, application through spraying post-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0119	120%	no
	2 (gloves)		0.0037	37%	yes
Meta SPC 1 1, 4 & 6 (mixing/loading, application through dipping post-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0005	5%	yes
	2 (gloves)		0.00005	<1%	yes
Meta SPC 2 & 3 2, 3 & 6 (decanting,	1 (no PPE)	0.01	0.0133	133%	no

application through spraying post-milking and cleaning of equipment)	2 (gloves)		0.0038	38%	yes
Meta SPC 2 & 3 2, 4 & 6 (decanting, application through dipping pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0018	18%	yes
	2 (gloves)		0.0002	2%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, post-milking)

Residue values for post-milking disinfection, as derived in Table 5 of the section "Risk for consumers via residues in food" below, have been added to the estimated professional user exposure.

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake / AEL (%)	Acceptable (yes/no)
Meta SPC 1 1, 3 & 6 (mixing/loading, application through spraying post-milking and cleaning of equipment) + total dietary intake (2 x post milking)	1 (no PPE)	0.01	0.0178	178%	no
	2 (gloves)		0.0095	95%	yes
Meta-SPC 1 1, 4 & 6 (mixing/loading, application through dipping post-milking and cleaning of equipment) + total dietary intake (2 x post-milking)	1 (no PPE)	0.01	0.0063	63%	yes
	2 (gloves)		0.0058	58%	yes
Meta-SPC 2 & 3 2, 3 & 6 (decanting, application through spraying post-milking and cleaning of equipment) + total dietary intake (2 x post-milking)	1 (no PPE)	0.01	0.0191	191%	no
	2 (gloves)		0.0096	96%	yes
Meta-SPC 2 & 3 2, 4 & 6 (decanting, application through dipping post-milking and cleaning of equipment) + total dietary intake (2 x post-milking)	1 (no PPE)	0.01	0.0076	76%	yes
	2 (gloves)		0.0060	60%	yes

Combined scenarios from primary exposure (2 milking events per day, pre- and post- milking)

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

			bw/d	(%)	
Meta SPC 1 1, 3, 5 & 6 (mixing/loading, application through spraying pre- plus post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0261	261%	no
	2 (gloves)		0.0076	76%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0034	34%	yes
Meta SPC 1 1, 4, 5 & 6 (mixing/loading, application through dipping pre- plus post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0030	30%	yes
	2 (gloves)		0.0003	3%	yes
Meta SPC 2 2, 3, 5 & 6 (decanting, application through spraying pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0274	274%	no
	2 (gloves)		0.0078	78%	yes
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0035	35%	yes
Meta SPC 2 & 3 2, 4, 5 & 6 (decanting, application through dipping pre- and post-milking, removal of freshly applied product pre-milking and cleaning of equipment)	1 (no PPE)	0.01	0.0043	43%	yes
	2 (gloves)		0.0004	4%	yes

Combined scenarios from primary exposure + total dietary intake (2 milking events per day, pre- and post- milking)

Residue values for pre- and post-milking disinfection, as derived in Table 5 of the section "Risk for consumers via residues in food" below, have been added to the estimated professional exposure.

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

Meta SPC 1 1, 3, 5, 6 (mixing/loading, application through spraying pre- plus post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0329	329%	no
	2 (gloves)		0.0144	144%	no
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0102	102%*	yes
Meta-SPC 1 1, 4, 5 & 6 (mixing/loading, application through dipping pre- plus post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0098	98%	yes
	2 (gloves)		0.0071	71%	yes
Meta-SPC 2 2, 3, 5 & 6 (decanting, application through spraying pre- and post- milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0342	342%	no
	2 (gloves)		0.0146	146%	no
	3 (gloves, coveralls & boots for spraying, gloves for other activities)		0.0103	103%*	yes
Meta-SPC 2 & 3 2, 4, 5 & 6 (decanting, application through dipping pre- and post-milking, removal of freshly applied product pre-milking and cleaning of equipment) + total dietary intake (2 x pre and 2 x post milking)	1 (no PPE)	0.01	0.0112	112%	no
	2 (gloves)		0.0073	73%	yes

* Marginal exceedances of the AEL are seen for spray application (102% of the AEL for meta-SPC 1 and 103% of the AEL for meta-SPCs 2 & 3). This value also includes background levels of iodine

from other sources (200 µg/day from milk and 185 µg/day from other sources for adults equivalent to 64% of the UL) therefore it should be noted that the unacceptable risk identified for professional adults is mainly due to exposure to iodine from sources other than the biocidal use. It is noted that WHO derived a value of 1000 µg/d for people in general therefore the limit values used in this assessment are considered conservative. As such, the UK CA considers that risk for a professional applying the product through manual spraying is acceptable.

Local effects

Iodine has an OEL (occupational exposure limit) of 1 mg/m^3. The iodine air concentration is not expected to exceed this limit from the proposed uses of the Deosan Activate BPF therefore the risk from local effects is considered acceptable.

Task/ Scenario	**Tier**	**Estimated air concentration (mg/m^3)**	**OEL value (mg/m^3)**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario 1- mixing /loading of concentrate (meta-SPC 1)	1	negligible	1	n.a.	Yes
Scenario 2- decanting of RTU product (meta-SPC 2 & 3)	1	negligible	1	n.a.	Yes
Scenario 3- application through manual spraying	1	4.6×10^{-2}	1	5%	yes
Scenario 4- manual application through the use of dipping cups	Covered by scenarios 1 & 2				
Scenario 5- removal of freshly applied product (pre-milking)	1	negligible	1	n.a.	Yes
Scenario 6- cleaning of manual/semi-automated equipment	1	negligible	1	n.a.	Yes
Scenario 7: transfer of product via connecting lines	1	Covered by scenario 2			
Scenario 8: automated spraying	1	No exposure expected			
Scenario 9: semi-automated dipping	1	Covered by scenario 4			

Conclusion

It is necessary to consider combined exposure to iodine from primary exposure during application of the Deosan Activate BPF and total dietary intake (agreed at the human health WG IV, 2017). For adults, a total dietary intake of iodine resulting from other dietary sources, the baseline milk value and the estimated iodine resulting from the proposed biocidal product use is 0.409 mg for pre- and post- milking, 0.337 mg for pre-milking and 0.347 mg for post- milking. These values are equivalent to 68% of UL for pre- and post- milking, 56% of the UL for pre- milking only and 58% of the adult UL for post-milking. . For detailed dietary exposure calculations, please refer to 'Risk for consumers via residues in food' section below. When taking into account primary exposure from application of the Deosan Active BPF and total dietary intake, the following conclusions can be made:

For meta-SPC 1

- Pre-milking: Acceptable combined exposure equivalent to 86% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 96% of the AEL is calculated for application via spraying with the use of gloves.
- Post-milking: Acceptable combined exposure equivalent to 63% of the AEL for application via manual dipping is calculated without the use of PPE (this estimate forms a risk envelope semi-automated dipping). Combined exposure equivalent to 95% of the AEL is calculated for application via spraying with the use of gloves.
- Pre- and post- milking: Acceptable combined exposure equivalent to 98% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 102% of the AEL is calculated for application via spraying with the use of gloves, boots and coated coveralls.

For meta-SPC 2

- Pre-milking: Acceptable combined exposure equivalent to 100% of the AEL is calculated for application via dipping without the use of PPE. Combined exposure equivalent to 97% of the AEL is calculated for application via spraying with the use of gloves.
- Post-milking: Acceptable combined exposure equivalent to 76% of the AEL for application via manual dipping without the use of PPE (this estimate also forms a risk envelope for semi-automated dipping). Combined exposure equivalent to 96% of the AEL is calculated for application via spraying with the use of gloves.
- Pre- and post- milking: Acceptable combined exposure equivalent to 73% of the AEL is calculated for application via dipping with the use of gloves. Combined exposure equivalent to 103% of the AEL is calculated for application via spraying with the use of gloves, boots and coated coveralls.

For meta-SPC 3

- Pre-milking: Acceptable combined exposure equivalent to 100% of the AEL is calculated for application via dipping without the use of PPE.
- Post-milking: Acceptable combined exposure equivalent to 76% of the AEL for application via manual dipping without the use of gloves (this estimate also forms a risk envelope for semi-automated dipping).
- Pre- and post- milking: Acceptable combined exposure equivalent to 73% of the AEL is calculated for application via dipping with the use of gloves.

On the basis of the risk assessment and considering that Deosan Activate BPF is not classified with respect to human health, the following PPE phrases are required:

Meta SPC 1 - concentrates	
Use 1 (pre-milking, manual dipping)	-

Use 2 (pre-milking, manual foaming)	-
Use 3 (pre-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 4 (post-milking, manual dipping)	-
Use 5 (post-milking, manual foaming)	-
Use 6 (post-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 7 (post-milking, automatic spraying)	-
Use 8 (post-milking, semi-automatic dipping)	-
Use 9 (pre- and post- milking, manual dipping)	-
Use 10 (pre- and post- milking, manual foaming)	-
Use 11 (pre- and post- milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information) Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn
Meta SPC 2 – RTU liquid	
Use 12 (pre-milking, manual dipping)	-
Use 13 (pre-milking, manual foaming)	-
Use 14 (pre-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 15 (post-milking, manual dipping)	-
Use 16 (post-milking, manual foaming)	-
Use 17 (post-milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the

	authorisation holder within the product information)
Use 18 (post-milking, automatic spraying)	-
Use 19 (post-milking, semi-automatic dipping)	-
Use 20 (pre- and post- milking, manual dipping)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 21 (pre- and post- milking, manual foaming)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
Use 22 (pre- and post- milking, manual spraying)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information Wear suitable protective footwear (EN 13832) when applying the product. A protective coverall (at least type 6, EN 13034) shall be worn
Meta SPC 3 – RTU gel	
Use 23 (pre-milking, manual dipping)	-
Use 24 (post-milking, manual dipping)	-
Use 25 (post-milking, semi-automatic dipping)	-
Use 26 (pre- and post- milking, manual dipping)	Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)

Risk for non-professional users

The Deosan Activate product family is not intended for use by non-professional users.

Risk for the general public

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

Risk for consumers via residues in food

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

	Adults (0.45 L)	Infants (0.46 L)
	Estimated daily intake (µg/day) [% of UL]	Estimated daily intake (µg/day) [% of UL]
2x pre-milking applications (0.32 % iodine)		
Intakes from proposed teat treatment	62 [10.3 % UL]	63 [31.6 % UL]
Total milk intake†	152 [25.3 % UL]	155 [77.6 % UL]
Total dietary intake‡	337 [56.2 % UL]	251 [125.6 % UL]
2x post-milking applications (0.32 % iodine)		
Intakes from proposed teat treatment	72 [12.0 % UL]	74 [36.9 % UL]
Total milk intake†	162 [27.0 % UL]	166 [82.9 % UL]
Total dietary intake‡	347 [57.9 % UL]	262 [130.9 % UL]
2x pre- and 2x post-milking (0.32 % iodine)		
Intakes from proposed teat treatment	134 [22.4 % UL]	137 [68.6 % UL]
Total milk intake†	224 [37.4 % UL]	229 [114.6 % UL]
Total dietary intake‡	409 [68.2 % UL]	325 [162.6 % UL]

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

Conclusions

Exposure assessment

For the realistic assumed application frequency (i.e. 2x pre- and 2x post-milking treatments) estimated dietary intakes of iodine the following conclusions can be made:

For adults, the estimated daily intake of iodine resulting from the realistic assumed application frequency, proposed biocidal product use is 22.4 % of the UL. When this additional iodine is added to the baseline milk value the daily intake of iodine from milk consumption is 37.4 % of the UL. Finally, a total dietary intake of iodine resulting from

other dietary sources, the baseline milk value and the estimated iodine resulting from the worst case proposed biocidal product use is 68.2 % of the UL.

For infants, the estimated daily intake of iodine resulting from the realistic assumed application frequency, proposed biocidal product use is 68.6 % of the UL. When this additional iodine is added to the baseline milk value the daily intake of iodine from milk consumption is 114.6 % of the UL. Finally, a total dietary intake of iodine resulting from other dietary sources, the baseline milk value and the estimated iodine resulting from the worst case proposed biocidal product use is 162.6 % of the UL.

The exceedance of the UL as a result of iodine intake is not a new issue. The 'UK retail survey of iodine in UK product dairy foods' [REF 6] noted exceedances of the PMTDI (Provisional Maximum Tolerable Daily Intake = 0.017 mg/kg bodyweight/day). It was however noted that these exceedances result from worst case exposure scenarios and the occasional exceedance of the PMTDI would not be of concern.

Another notable example of exceedance of the UL was reported in an EFSA scientific opinion of the safety and efficacy of iodine compounds, [REF 9]. In this paper it was stated that: *'The iodine content of food of animal origin, if produced from animals receiving the currently authorised maximum contents of total iodine in complete feed for dairy cows and laying hens (5 mg/kg), would represent a substantial risk to consumers, mainly for high-consuming (95th percentile) adults and toddlers. The risk would originate primarily from the consumption of milk and, to some extent, from consumption of eggs. The ULs would for adults be exceeded by a factor of 2 (1230 vs. 600 µg I/day), and for toddlers by a factor of 4 (840 vs. 200 µg I/day).'* As a result of these exceedances the FEEDAP Panel recommended a reduction in the currently authorised maximum iodine contents in complete feed.

Contribution from other sources

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

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

The use of the iodine teat treatments could potentially contribute to the levels found in groundwater. As part of the environmental risk assessment PEC have been estimated. However, the main issue with these estimated PEC is that they are significant over estimates as they are done as a porewater calculation so do not account for any means of dissipation at all i.e. binding to organic matter, plant uptake, lateral transfer. In addition, assuming that 100 % drinking water comes from groundwater could be an overestimate; the proportion of drinking water that is sourced from groundwater sources varies from region to region.

With no agreed background levels of iodine in water, no agreed proportion of water sourced as groundwater and with significantly overestimated PEC values for the iodine teat treatment uses then at this time a consumer risk assessment including water would

be subject to a high level of uncertainty. However, this issue should be a part of the consideration by MS/ECHA/EFSA in obtaining more reliable information on the sources of iodine in the diet.

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

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

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

1. Feed supplementation
2. Food and salt supplementation
3. Dietary supplements

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

UK decision

Based on the estimated total intakes for adults, the human health risk is acceptable in all milking applications. In contrast, the estimated total daily intake for toddlers exceeds the UL in all scenarios. It is noted that for toddlers, exceedance of the UL is almost obtained already from dietary intakes arising from iodine background levels (milk from untreated teats and diet), rather than the teat treatment alone. Furthermore, it is generally reported that the main contributor for iodine levels in milk is animal feed (natural sources and supplementations). Ideally, further work should be performed to obtain more reliable information on iodine background levels in food items in the EU. Moreover,

it should be mentioned that by using the agreed upon values for background in milk and other dietary sources leads to 94 % of UL for toddlers.

The following options are available for a risk management decision as to whether authorisation can be granted:

1. No authorisation of the product: The estimated total daily intakes exceed the UL for toddlers and are unacceptable.
2. Authorise: The estimated total daily intakes exceed the UL for toddlers; however post authorisation data should be submitted to resolve some of the uncertainties surrounding this risk assessment. These data should include milk residue studies/trials following application of the product.
3. Authorise: Whilst there are exceedances, a socio-economic comparative assessment should be undertaken to show that the benefits outweigh the risks.
4. Authorise: Exceedances of the UL are seen already with dietary intakes arising from iodine background levels. The additional burden arising from teat disinfection is regarded to be of little consequence.

For consideration by MS/ECHA/EFSA: More reliable information on iodine background levels in food items in the EU and a more recent review of all the available data supporting the current UL are required. For the background levels all sources of iodine, and not just those arising from teat treatments, would need to be taken into consideration. Therefore a wider approach to the consumer risk assessments encompassing different regulatory regimes would need to be considered.

Option 2, asking for post authorisation data was discussed in the CA 74 (September 2017) and the majority did not support this proposal. Furthermore, it was acknowledged that biocides are not the main contributor of the exposure level and more discussion was needed.

The outcome of the risk management decision will be specified in the BPC opinion following discussions at the BPC-26 meeting of the Biocidal Products Committee (BPC).

References

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

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

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

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

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

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

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

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

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

2.2.7 Risk assessment for animal health

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

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

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The product family contains only one active substance and no substances of concern. Therefore all toxicity data can be obtained from the CAR. The PNECs are summarised below:

STP:

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

Iodide and iodate: no PNEC derived in the CAR (2013) on iodine.

Aquatic compartment:

Iodine: $PNEC(I_2)_{aquatic}$ = 0.59 µg iodine/L
Iodate: $PNEC(IO_3^-)_{aquatic}$ = 58.5 µg iodine/L
Iodide: $PNEC(I^-)_{aquatic}$ = 0.83 µg iodine/L

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

According to the CAR:The natural background levels of iodine in freshwater sediments is typically 6 mg/kg. Thus, in analogy with the $PNEC_{aquatic}$ the derived $PNEC_{sediment}$ values are very conservative and may be regarded as unrealistic. Given that both PEC's and PNEC's are calculated using the partitioning equilibrium method, the derived PNEC's are therefore provided for information but will not be used in the risk assessment.

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

Terrestrial compartment:

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

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

No additional data are required.

Further Ecotoxicological studies

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

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

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

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

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

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

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

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

No additional data are required.

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

The products are intended for use as teat-disinfectants for dairy cows and other milkable animals. They are used in animal houses (in-door use) and are applied by dipping,

foaming or spraying to the teats of the animals before and/or after milking. Exposure to the environment is always secondary, via liquid manure and STP. Exposure to air is not relevant due to the low vapour pressure of the active substance. The main route of exposure to the environment is via liquid manure to arable land and grassland. When applying the products to the animal teats by spraying, spray may not reach the animal teats or part of the product applied to the teats may be lost by drip formation. Drip formation may also occur when the products are applied by dipping. Droplets from teat dip/spray solution may drip on the milking parlour floor after application. As a worst case scenario, it is assumed that 50% of product applied on the teats drips on to the floor (according to the Emission Scenario Documents (ESD) for PT3). Potential spilled solution can either reach the manure or the waste water, depending on whether the cows are milked in the stable (emission to manure) or in a milking parlour (emission to wastewater). Considering that most farms are not connected to the municipal sewer, waste water is often released to the manure depot instead. If present, residues may be released to individual sewage treatment plants as well when equipment is for instance rinsed above sinks. In all other cases release to the municipal sewer and subsequently to a sewage treatment plant (STP) is likely. If applied post-milking, the products will only partly remain on the animal teats between two milking events. The part which simply falls off or is lost due to contact with the surfaces (e.g. when the cows lie down for rest) will finally end up in the liquid manure. The part remaining on the teats will be removed before the next milking by wiping with a dry cloth or a single paper towel. If disposable tissues are used, the product will end up in the waste bin; if reusable cloths are used (which is not recommended), the removed product will end up in the drain when the cloth are cleaned / washed after the milking.

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

Not needed since available data set is sufficient for the risk assessment.

Leaching behaviour (ADS)

Not applicable for the uses assessed.

Testing for distribution and dissipation in soil (ADS)

No new data is available. Data reported in the CAR is sufficient for the risk assessment.

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

No new data is available. Data reported in the CAR is sufficient for the risk assessment.

Testing for distribution and dissipation in air (ADS)

No new data is available. Data reported in the CAR is sufficient for the risk assessment.

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

Not applicable, product is not sprayed near surface waters.

Acute aquatic toxicity

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

Chronic aquatic toxicity

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

Measured aquatic bioconcentration
No additional data are required.

Estimated aquatic bioconcentration

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

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

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

2.2.8.2 Exposure assessment

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

The following exposure assessment is performed for the scenario "Disinfection of teats of dairy cows". The teat disinfection of dairy cows is the most important use of the products of the BPF, but not limited to this use. The products can also be used for the disinfection of the teats of buffaloes, sheep and goats.
The applicant has requested that the following exposure assessment for cows is also applicable to the use in buffaloes, sheep and goats:

- Buffaloes: equal to dairy cows, buffaloes have four teats. The application rate per animal and milking is equal to dairy cows. Since buffaloes are only milked two times a day, the iodine emission to the environment due to the use of teat disinfectants is lower than for a herd of dairy cows (assuming the same number of animals per herd).
- Sheep and goats: these animals have only two teats per animal resulting in application rates per animal of 5 mL (sheep) and 6 mL (goats) for dipping and

spraying and 2.5 mL (sheep) to 3 mL (goats) for foaming. The animals are only milked 1-2 times per day.

It is therefore concluded that the exposure assessment for dairy cows covers buffaloes, sheep and goats.

General information

Assessed PT	PT 3
Assessed scenarios	Scenario 1: Disinfection of teats of dairy cows
ESD(s) used	Emission Scenario Document for Product Type 3 Veterinary hygiene biocidal products EUR 25116 EN - 2011
Approach	Scenario 1: Average consumption The products can either be applied by • manual dipping: pre, post or pre&post (product volume of 10 ml/cow/milking) or • semi-automatic dipping : post (product volume of 10 ml/cow/milking) or • foaming: pre, post, pre&post (product volume of 5 ml/cow/milking) or • automatic (robotic) spraying: post (product volume of 15 ml/cow/milking) or • spraying: pre, post or pre&post (product volume of 15 ml/cow/milking). Since spraying results in the highest application rate per day, it is assessed as worst case. Consequently, the dipping (manual or semi-automatic), foaming and automatic (robotic) spraying application are covered by the spraying scenario.
Distribution in the environment	In agreement with the CAR (2013) on iodine.
Groundwater simulation	Not performed. The calculation of the concentration in groundwater was performed according to the approach described in the Guidance on BPR, Volume IV, Part B where the concentration in porewater of agricultural soil is used as a first indication for groundwater concentrations. In the CAR for iodine PECgw values for PT3 were calculated based on the PECsoil for application to grassland and arable land. Uses were considered acceptable if the calculated iodine concentrations in groundwater were above the mean natural background concentration of 1 µg/L but they were still below the maximum natural background concentration of iodine of 70 µg/L.
Confidential Annexes	No
Life cycle steps assessed	Production of active substance iodine: not assessed; the production takes place outside the EU. Formulation: assessed (statement) Use: assessed Service life: not assessed, not relevant: no service life after application
Remarks	-

Emission estimation

Formulation of the product:
The whole formulation process is conducted indoor under industrial quality and safety conditions. Closed stainless steel mixers with automatic dosing equipment and lids for manual addition of smaller amounts of liquids and solids/powders are used. The mixer is equipped with air extraction to prevent emission of the chemicals to the environment. After quality control the finished product is pumped to filling lines where the product is filled into various containers: 1, 5 & 20 L cans, 200 L drums and 1000 L IBCs. If not directly filled up it is pumped into a holding tank, where it is de-aerated and stored until it is filled into the sale packages. The formulation is done in a closed system. Any spillage during production is absorbed with inert material (sand, earth, chemical absorbent, etc.) and collected in dedicated drums properly labelled, and disposed of as chemical waste via an approved waste management organisation in accordance with local and national laws and regulations. Consequently, there is no release into the environment and therefore, an environmental exposure and risk characterisation for the production step is not applicable.

Scenario 1: Disinfection of teats of dairy cows

Teat disinfections are applied by manual or semi-automated-dipping, by foaming, or by manual or automated spraying. The latter applies when the cows are milked by a robot. All products within the product family are used at the same concentration, with concentrate products being diluted prior to use to match the concentration in the RTU products. The respective application rates for the products are provided in the following table. As already mentioned in the table "General information" above, spraying can be considered as worst-case covering also the other types of application.
The applicant has based their risk assessment on a maximum number of three milkings per day. They have considered that when robotic milking is applied, individual cows maybe milked up to 5 times per day, in exceptional cases even up to 6 times. However, the average milking frequency per day per herd is always below 3 milkings per day (experience from a test house specialised in veterinary farm research member). Consequently, the maximum number of milking events is 3 per day also for robotic milking. It is noted that the ESD (2011) for PT3 indicates that an average assessment of two milkings per day is acceptable.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Teat disinfection of animals			
Application rate of biocidal product	5	ml/cow/milking	for the application method foaming
Application rate of biocidal product	10	ml/cow/milking	for the application method dipping
Application rate of biocidal product	15	ml/cow/milking	for the application method spraying
Concentration of active substance in the product	0.439	%	Calculated from the max. in-use-concentration of 0.32% iodine and the max.

			concentration of 0.14 % sodium iodide in the applied products*****
Time of application	pre & post	-	-
Number of milking events per day	3	d^{-1}	Pre and post treatments during each milking event
Resulting product volume for foaming	30	ml/cow/day	Maximum daily amount for 3 pre & post applications per day
Resulting product volume for dipping	60	ml/cow/day	
Resulting product volume for spraying	90	ml/cow/day	

***** Please refer to the explanations provided in: 2.2.6.2 Risk assessment for human health, B. Exposure assessment/General considerations

Calculations for Scenario 1:

The calculations sheets for the emission estimation, based upon the ESD for PT3 teat dip applications are attached in Annex 3.2.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal $_{wastewater)}$**	**Remarks**
STP	0.0162 kg/d	Daily emission to the sewer system
	Local emission (PIEC)	
SOIL - Immission standard for phosphate -grassland	Iodine/iodide: 0.061 mg/kg_{wwt} Iodate: 0.084 mg/kg_{wwt}	for pre- plus post-milking disinfection
SOIL - Immission standard for phosphate- arable land	Iodine/iodide: 0.047 mg/kg_{wwt} Iodate: 0.065 mg/kg_{wwt}	for pre- plus post-milking disinfection
SOIL - Immission standard for nitrogen-grassland	Iodine/iodide: 0.029 mg/kg_{wwt} Iodate: 0.04 mg/kg_{wwt}	for pre- plus post-milking disinfection
SOIL - Immission standard for nitrogen-arable land	Iodine/iodide: 0.029 mg/kg_{wwt} Iodate: 0.04 mg/kg_{wwt}	for pre- plus post-milking disinfection

According to the ESD for PT3, the deposition of active substances onto agricultural land (grassland) by manure/ slurry is estimated on the basis of emission standards for nitrogen or phosphate. Depending on the amount of nitrogen or phosphate in manure and the type of soil to which it is applied, these emission standards define the maximum amount of manure/slurry that can be applied per hectare and per year. The concentration in soil after manure/slurry application at maximum permissible rate (170 kg N/ha for both grassland and arable land and 110 kg P_2O_5/ha for grassland and 85 kg P_2O_5/ha for arable land) is calculated using the equations as proposed in the ESD for PT3. The PIECs calculated for application to grassland and arable land are presented for both nitrogen and phosphate in the table above. It is noted that the focus for the iodine species should be on the nitrogen standard as it is the nitrogen emission standards that limit the emission to the environment for dairy cows. Therefore these values have been taken forward for the determinations of PECs in the risk assessment.

Fate and distribution in exposed environmental compartments

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

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

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

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

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

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

Source: ECHA Although iodine (I_2) may evaporate as the vapour pressure is 40.7 Pa, it cannot be expected that ionised iodine species are volatile. Therefore, emission to air was not considered.

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

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	n.r.	CAR (2013) on iodine
Water	80	CAR (2013) on iodine
Sludge	20	CAR (2013) on iodine
Degraded in STP	0	CAR (2013) on iodine

Calculated PEC values

In the following tables the calculated PEC values for iodine and its transformation products iodide and iodate are provided for the proposed worst use of 15ml, pre- plus post- milking treatment by spraying.

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

The emission to soil from the application of sewage sludge has been determined using equations 54 and 62 from the ECHA guidance on BPR Vol IV part B for each of the different soil types to give PEC $local_{agrsoil}$ and PEC $local_{grasssoil}$ values. The input values from the iodine CAR were used (Doc IIB, Appendix II, page 123). Leaching was taken into account in the calculation (using equation 58) of the first order rate constant for removal from top soil), and PECsoil values are based on $C_{sludgesoil10}$ values (the initial concentration after application of sludge in the 10th year).

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

The emission to soil from the application of slurry/manure has been determined based upon the nitrogen immission standard for grassland, four applications per year and 10 consecutive years loading with leaching in soil (equation 58). This has been calculated in accordance with the Technical Agreements for Biocides (TAB) version 1.3 (August 2017), ENV125 (AHEE Recommendation for PT 18 (WG-V-2015)), with the additional amendment that the $Tgr\text{-}int_{no\_manure}$ value for application to grassland has been amended to 365 days as agreed at WG-I-2018.

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

The field PEC $local_{soil}$ value was applied to the equation 68 from the ECHA guidance on BPR Vol IV part B. For the emissions through STP, the transformation as described above is assumed for iodine, iodide and iodate.

Summary table on calculated PEC values						
Scenario 1a (via STP)						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[µg/l]	[µg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
	6.48	0.648 iodine/iodide 0.895 iodate	0.031 iodine/iodide 0.043 iodate	0.0437 iodine 0.006 iodide 0.06 iodate	8.35 iodine 1.17 iodide 11.54 iodate	--
Scenario 1b (via slurry/manure)						
Nitrogen standard, grassland	--	6.09 iodine/iodide* 8.42 iodate	0.297 iodine/iodide 0.41 iodate	0.32 iodine/iodide 0.44 iodate	61.12 iodine/iodide 84.47 iodate	--
Nitrogen standard, arable land	--	3.69 iodine/iodide* 5.11 iodate	0.18 iodine/iodide 0.25 iodate	0.194 iodine/iodide 0.268 iodate	37.06 iodine/iodide 51.2 iodate	--
*Following consideration of PEC_{GW} value following manure/slurry application, PECs in surface water were calculated using the approach provided in the ESD for PT18 (OECD no. 14) on page 58 and a standard run-off dilution factor of 10 was applied to the PEC_{qw} value. In addition these values were also corrected for sorption onto suspended matter to give values of 6.09 µg/L iodine/iodide and 8.42 µg/L iodate.						

Primary and secondary poisoning

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

2.2.8.3 Risk characterisation

The risk assessment below has considered the worst case PEC value for each compartment, which for Scenario 1b is based upon the emissions via application to grassland. In the risk assessment, when the PEC/PNEC values are calculated to be above 1, comparison with the natural background levels in the concerned compartment is made. According to the CAR (2013) on iodine the PEC/PNEC values above 1 are acceptable, if the PEC-values are within the background concentrations.

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

Background concentration of iodine in the environment	
Compartment	**natural background concentration**
Air	-
STP	-
Surface water	0.5 – 20 µg iodine/L
Rain water	0.1 – 15 µg iodine/L
Fresh water sediment	typically 6 mg iodine/kg
Sea water	45 - 60 µg iodine/L
Maine sediment	3 - 400 mg iodine/kg
Soil	0.5 – 20 mg/kg_{dwt} with extremes up to 98 mg/kg_{dwt} (corresponding to 0.4 - 18 mg iodine/kg_{wwt} with extremes up to 86 mg/kg_{wwt})
Groundwater	< 1-70 µg iodine/L (with extremes up to 400 µg/L)

Atmosphere

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

Sewage treatment plant (STP)

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

Summary table on calculated PEC/PNEC values	
	PEC (mg/L)/$PNEC_{STP}$ (mg/L)
Scenario 1a	0.00648/2.9 = 2.23E-03

Conclusion: There is no information on the relative distribution of iodine, iodide and iodate in an STP, therefore only total iodine is presented; PNEC STP = 2.9 mg/L (CAR iodine). The individual PEC/PNEC ratio for the STP scenario for iodine is below the trigger value of 1. The results of the risk characterisation show that there is no unacceptable risk for the relevant compartment from the proposed use of the teat disinfectant products.

Aquatic compartment

iodine:	$PNEC(I_2)_{aquatic}$	= 0.59 µg iodine/L
iodate:	$PNEC(IO_3^-)_{aquatic}$	= 58.5 µg iodine/L
iodide:	$PNEC(I^-)_{aquatic}$	= 0.83 µg iodine/L

The PEC-values and also the PNEC-values for the sediment compartment are calculated with the equilibrium partitioning method based on the $PEC_{aquatic}$ and $PNEC_{aquatic}$, respectively. Consequently, the PEC/PNEC values for the sediment are identical to the PEC/PNEC-values for the aquatic compartment. It is also noted that the calculated maximum PEC's 0.297 mg/kg and 0.41 mg/kg for iodine/iodide and iodate respectively (via run off)) are well below the natural background levels of fresh-water sediments i.e. typically 6 mg iodine/kg (CAR on iodine, 2013).

Summary table on calculated PEC/PNEC values	
	PEC (µg/L)/$PNEC_{water}$ (µg/L)
Scenario 1a (STP)	0.648/0.59 = **1.10** 0.648/0.83 = 0.78 0.895/58.5 = 0.015
Scenario 1b (run off) worst case values from slurry/manure application to grassland	Iodine 6.09/0.59 = **10.32** Iodide 6.09/0.83 = **7.34** Iodate 8.42/58.5 = 0.14

Conclusion: The freshwater assessment is conducted based on the estimated worst case freshwater values arising from run off following application of slurry manure to grassland, therefore consideration has also been made of the iodide and iodate species for his compartment.

For surface water the PEC/PNEC ratio is greater than 1 for both scenarios for iodine. As iodine is a naturally occurring substance PEC/PNEC values above 1 are acceptable, if the PEC-values are within the background concentrations (for more details see CAR on iodine (2013)). The maximum surface water concentration is 6.11 µg iodine/L. This value is within the natural background concentration in freshwater (river and lake) of 0.5-20 µg/L. Therefore, it is concluded that there is no unacceptable risk for the aquatic compartment from the proposed use of the teat disinfectant products.

The risk to marine water from the STP route can be considered to be covered by the assessment for freshwater. Because although the PNEC value for marine waters is 10 x less than for fresh water (in CAR for iodine 2013), the dilution is considered to be 10 x more therefore the PEC:PNEC ratio will be the same, hence marine PEC/PNEc ratios are not explicitly reported here.

Terrestrial compartment

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

In the following tables the calculated PEC/PNEC values for iodine and its transformation products iodide and iodate are provided:

Calculated PEC/PNEC values	
	PEC (mg/kg)/$PNEC_{soil}$ (mg/kg)
Scenario 1a (via STP)	iodine 0.0437/0.0118 = **3.7** iodide 0.0059/0.0043 = **1.37** iodate 0.059 / 0.304= 0.19
Scenario 1b (via slurry/manure) worst case values from slurry/manure application to grassland considered	iodine 0.32/0.0118 = **27** iodide 0.32/0.0043 = **74.4** iodate 0.44/0.304 = **1.45**

Conclusion:

The individual PEC/PNEC ratios exceed 1.0 for both sewage sludge and slurry / manure application.

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

The PEC values for iodine/iodide and iodate in the calculation described above (section *B. Exposure Assessment*) are in the range of 0.32 – 0.44 mg/kg_{wwt} and are towards the lower limit of the background concentrations for iodine.

Therefore, it is concluded that there is no unacceptable risk for soil from the proposed use of the teat disinfectant products.

Groundwater

The calculated PEC_{gw} values are above the limit values of 0.1 µg/L provided for pesticides in the Drinking Water Directive 98/83/EC.
However, it is stated in the CAR (2013) that the trigger value of 0.1 µg/L is limited to organic substances and their relevant metabolites and degradation products. Since iodine and its species are inorganic substances, which are not xenobiotic but essential nutrients, it is concluded in the CAR that the concentration of 0.1 µg/L for pesticides is not applicable.
The maximum estimated values in the calculations above are 61.12 µg/L for iodine/iodide and 84.47 µg/L iodate, which are based upon the worst case values from slurry/manure application to grassland. The CAR for iodine (2013) indicates that natural background levels of iodine in groundwater are reported as 1- 70 µg/L, with some extreme levels of 400 µg/L being noted. These emission estimate values are therefore above the mean natural background concentration of 1 µg/L, but they are still below the maximum natural background concentration of 70 iodine µg/L as provided in the CAR (2013).

In addition, the PEC values in groundwater were calculated following the approach described in the Guidance on the BPR Volume IV, Part B using the porewater concentration in soil as indication for the groundwater level i.e. the calculation assumes all the active in the soil porewater is carried through to groundwater and no removal, dilution or transformation processes like e.g. lateral transport or plant uptake are taken into account. Therefore, the calculated concentration is an overestimate of the likely concentrations in groundwater.

Primary and secondary poisoning

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

Aggregated exposure (combined for relevant emmission sources)

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

Overall conclusion on the risk assessment for the environment of the product
The Deosan Activate product family is made up of teat disinfectant products consisting of ready to use formulations and a concentrate that is diluted prior to use. All products within the product family are used at the same in use concentration; concentrate products are diluted prior to use to match the concentration in the RTU products. The in use concentration is 0.439 % total iodine (sum of available iodine and iodide from sodium iodide). The use of the product applied both pre and post-milking, by foaming, dipping or spraying (max 15 mL/cow/application) at a herd average of 3 milkings per day has been assessed. This results in a total application of 90 mL of diluted product/cow/day. In line with the consideration in the CAR on iodine (2013) the assessment is performed for iodine, iodide and iodate (expressed as total iodine). In the risk assessment, PEC/PNEC values less than 1.00 indicate an acceptable risk. The individual PEC/PNEC ratio for the STP scenario 1a for iodine is below the trigger value of 1. However, as iodine is a naturally occurring substance PEC/PNEC values above 1 are acceptable, if the PEC-values are within the natural occurring background concentrations (for more details see CAR on iodine 2013). The PEC/PNEC ratios for the terrestrial environment and surface water are above 1.0. Therefore a comparison has been made against the naturally occurring levels in these compartments: The maximum surface water PEC is 6.09 µg iodine/L, which is within the natural background concentration of iodine in freshwater (river and lake) of 0.5-20 µg/L. The PEC values for iodine/iodide and iodate in soil are in the range of 0.32 – 0.44 mg/kg_{wwt} which are below the lower limit of the background concentrations for iodine in soil of 0.4 -18.0 mg/kg_{wwt} soil. The maximum estimated levels in groundwater are 61.12 µg/L for iodine/iodide and 84.47 µg/L iodate. These values are below the maximum natural background concentration of 70 µg iodine/L.

Therefore, it is concluded that there is no unacceptable environmental risk from the proposed use of the Deosan Activate teat disinfectant products.

2.2.9 Measures to protect man, animals and the environment

Please see section 1.2 of this PAR 'Issues to be accounted for in the product label' and sections 2.1.4.3 to 2.1.4.5 for relevant measures to protect man, animals and the environment.

2.2.10 Assessment of a combination of biocidal products

Not applicable, Deosan Activate is not intended to be used with other biocidal products.

2.2.11 Comparative assessment

Iodine is not a Candidate for Substitution as it does not meet the criteria stated in Article 10 of Regulation (EU) 528/2012. A comparative assessment is therefore not required under Article 23 of Regulation (EU) 258/2012.

3 Annexes[7]

3.1 List of studies for the biocidal product (family)

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
5.1	[redacted]	2013	Set up and validation of a titrimetric method for the quantification of the active ingredient iodine in the test item "Deosan Activate Barrier AG216 (FM009713)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2013-03028 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
5.1	[redacted]	2013	Set up and validation of a titrimetric method for the quantification of the active ingredient iodine in the test item "Deosan Activate Pre AG106 (FM009714)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2013-03029 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
5.1	[redacted]	2013	Quantification of the active ingredient iodine in the test item "Deosan Activate PVP Plus AG215 (FM009710)" and specificity verification. Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2013-03030 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
5.1	[redacted]	2013	Quantification of the active ingredient iodine in the test item "Deosan Activate Pre/Post AG217 (FM009712)" and specificity verification. Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2013-03031 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
3.1/3.2	[redacted]	2014	Determination of Physical Appearance, pH and aciditiy/alcalinity of the Test Item "Deosan Activate Barrier AG216 (FM009713)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00023 AMi GLP; unpublished	Yes	Diversey Europe Operation BV

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

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
3.3	[redacted]	2014	Determination of density and relative density according to OECD 109 method on the test item "Deosan Activate Barrier AG216 (FM009713)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00024 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.9	[redacted]	2014	Viscosity of Liquids according to OECD 114/ CIPAC L-MT 192 on the Test item "DEOSAN ACTIVATE BARRIER AG216 (FM009713)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00025AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.1/3.2	[redacted]	2014	Determination of physical appearance, pH and Acidity/Alcalinity on the Test Item "Deosan Activate Pre AG106 (FM009714)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00026 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.3	[redacted]	2014	Determination of density and relative density according to OECD 109 method on the test item "Deosan Activate PRE AG106 (FM009714)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00027 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2014	Determination of Persistence of Foaming of Suspension Concentrates according to CIPAC MT 47.2 Method on the Test Item "Deosan Activate Pre AG106" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00028 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.7	[redacted]	2014	Determination of Dilution Stability according to CIPAC MT 41 Method on the Test Item "DEOSAN ACTIVATE PRE AG106" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00030AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.9	[redacted]	2014	Viscosity of Liquids according to OECD 114/ CIPAC L-MT 192 on the Test item "DEOSAN ACTIVATE PRE AG106 (FM009714)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-00031 AMi GLP; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
3.4.1.1	[redacted]	2014	Accelerated stability study for 8 weeks at 40°C/75%RH and Back up stability at 30°C/65%RH for 18 weeks on the Test Item "Deosan Activate Barrier AG216 (FM009713)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: 2014/1 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.4.1.1	[redacted]	2014	Accelerated stability study for 8 weeks at 40°C/75%RH and Back up stability at 30°C/65%RH for 18 weeks on the Test Item "Deosan Activate Pre AG106 (FM009714)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: 2014/2 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016a	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate PVP Plus AG215 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4054-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016b	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate PVP Plus AG215 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4057-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016c	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post AG217 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4058-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016d	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post AG217 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4060-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
6.7	[redacted]	2016e	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post AG217 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4061-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016f	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Barrier AG216 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4064-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016g	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Barrier AG216 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4065-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016h	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post Conc.AG218 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4071-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016i	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre AG106 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4073-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016	Final Report Efficacy of Deosan Activate product family, Phase 2 step 2 test protocol (modified EN 16437) Drop/Dip Report No.: EN16437_200916_BH GLP: no; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D51-2013 Version 2 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D51-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1657:2005/AC:2007 modified: Quantitative Suspension Test Yeasticidal Activity (additional conditions, teat disinfection) Laboklin GmbH & Co KG Report No.: D51-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D52-2013 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D52-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1657:2005/AC:2007 modified: Quantitative Suspension Test Yeasticidal Activity (additional conditions, teat disinfection) Laboklin GmbH & Co KG Report No.: D52-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D53-2013 GLP: no; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D53-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1657:2005/AC:2007 modified: Quantitative Suspension Test Yeasticidal Activity (additional conditions, teat disinfection) Laboklin GmbH & Co KG Report No.: D53-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D54-2013 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D54-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1657:2005/AC:2007 modified: Quantitative Suspension Test Yeasticidal Activity (additional conditions, teat disinfection) Laboklin GmbH & Co KG Report No.: D54-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1656:2009 (AC:2010) Quantitative Suspension Test Bactericidal Activity (teat disinfection, obligatory and additional conditions) Laboklin GmbH & Co KG Report No.: D73-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2014	Test Report EN 1657:2005/AC:2007modified Quantitative Suspension Test Yeasticidal Activity (additional conditions, teat disinfection) Laboklin GmbH & Co KG Report No.: D73-2014 GLP: no; unpublished	Yes	Diversey Europe Operation BV
3.9	[redacted]	2015	Viscosity of Liquids according to OECD 114 on the Test item "DEOSAN ACTIVATE PRE RTU AG108 (1:5 of FM009714)" Diversey Services Germany OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
3.9	[redacted]	2015	Viscosity of Liquids according to OECD 114/ on the Test item "DEOSAN ACTIVATE PRE/POST AG217 (FM009712)" Diversey Services Germany OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.9	[redacted]	2015	Viscosity of Liquids according to OECD 114 on the Test item "DEOSAN ACTIVATE PVP Plus AG215 (FM009710)" Diversey Services Germany OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2015	Photo documentation on the application of a teat-disinfectant foam Diversey Services Germany OHG Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2016a	Foam Stability On The Test Item "Deosan Activate Pre AG106 (FM009714)" Diversey Services Germany OHG Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2016b	Foam Stability On The Test Item "Deosan Activate Pre Post Conc AG218 (FM010201)" Diversey Services Germany OHG Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2016c	Foam Stability On The Test Item "Deosan Activate Pre AG106 (FM009714)" Diversey Deutschland GmbH & Co. OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.5.7	[redacted]	2016d	Foam Stability On The Test Item "Deosan Activate Pre Post Conc AG218 (FM010201)" Diversey Deutschland GmbH & Co. OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.2	[redacted]	2016e	pH On The Test Item "Deosan Activate Pre AG106 (FM009714)" Diversey Deutschland GmbH & Co. OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV
3.2	[redacted]	2016f	pH On The Test Item "Deosan Activate Pre Post Conc AG218 (FM010201)" Diversey Deutschland GmbH & Co. OHG, Mannheim, Germany unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
3.1	[redacted]	2015	Determination of Physical Appearance of the Test Item "Deosan Activate Pre/Post Conc (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-03198 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.2	[redacted]	2015	Determination of pH and Acidity/Alcalinity on the Test Item "Deosan Activate Pre/Post Conc (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-03199 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.3	[redacted]	2015	Determination of absolute density and relative density according to OECD 109 method on the test item "Deosan activate pre/post conc. (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-03200 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
3.7	[redacted]	2015	Determination of Dilution Stability according to CIPAC MT 41 Method on the Test Item "DEOSAN ACTIVATE PRE/POST CONC (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-03203 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
3.9	[redacted]	2015	Viscosity of Liquids according to OECD 114 Guidline on the Test item "DEOSAN ACTIVATE PRE/POST CONC (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: S-2014-03204 Ami GLP; unpublished	Yes	Diversey Europe Operation BV
5.1	[redacted]	2015	Set up and validation of a titrimetric method for the quantification of the active ingredient iodine in the test item "Deosan Activate Pre/Post CONC (FM010201)" Eurofins Biolab Srl, Vimodrone, Italy Report No.: S-2014-03206 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.4.1.1	[redacted]	2015	Accelerated Stability Study for 8 weeks at 40°C/75%RH on the Test Item "Deosan Activate Pre/Post Conc (FM010201)" Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: 2014/222 Ami GLP; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
3.4.1.2	[redacted]	2015	Control of Critical Parameters under Stability Conditions Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: 2014/3 AM GLP; unpublished	Yes	Diversey Europe Operation BV
3.4.1.2	[redacted]	2015	Control of Critical Parameters under Stability Conditions Eurofins Biolab srl, Vimodrone (MI), Italy Report No.: 2014/4 AM GLP; unpublished	Yes	Diversey Europe Operation BV
3.4.1.2	[redacted]	2016	Shelf-life stability study for 24 months at 25°C/60% RH on the test item "Deosan Activate Pre AG106 (FM009714)" Eurofins Biolab S.r.l., Vimodrone (MI), Italy Report No.: 2014/3 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
3.4.1.2	[redacted]	2016	Shelf-life satbility study for 24 months at 25°C/60%RH on the test item "Deosan Activate Barrier AG216 (FM009713)" Eurofins Biolab S.r.l., Vimodrone (MI), Italy Report No.: 2014/4 AMi GLP; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2015	Evaluation of the effectiveness of Deosan Activate PVP Plus AG215 Dr. Brill + Partner GmbH Institute for Hygien and Microbiology, Norderoog 2, DE-28259 Bremen D15L0278MV, GLP; unpublished	YES	Diversey Europe Operation BV
6.7	[redacted]	2015	Evaluation of the effectiveness of Deosan Activate Pre/Post Dr. Brill + Partner GmbH Institute for Hygien and Microbiology, Norderoog 2, DE-28259 Bremen D15L0445MV, GLP; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016a	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate PVP Plus AG215 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4055-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016b	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate PVP Plus AG215 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4056-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
6.7	[redacted]	2016c	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post AG217 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4059-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016d	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Barrier AG216 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4062-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016e	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Barrier AG216 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4063-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016f	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post Conc.AG218 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4069-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016g	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post Conc.AG218 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4070-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV

Section No./ Reference No.	Author(s)	Year	Title Source (laboratory) Report No. GLP; (un)published Doc. No.	Data protection (Yes / No)	Owner
6.7	[redacted]	2016h	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre/Post Conc.AG218 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4072-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016i	Efficacy test for bactericidal activity on a porous surface (VITRO SKIN® synthetic skin) according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre AG106 Test on Staphylococcus aureus DSM 799 LMH Expert microbiology, France Report No.: No.4074-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016j	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre AG106 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4075-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV
6.7	[redacted]	2016k	Efficacy test for yeasticidal activity on a synthetic skin according to a protocol adapted from the EN 16437 standard in drop/dip Deosan Activate Pre AG106 Test on Candida albicans DSM 1386 LMH Expert microbiology, France Report No.: No.4076-1 GLP: no; unpublished	Yes	Diversey Europe Operation BV

3.2 Output tables from exposure assessment tools

Exposure Risk Assessment

Figure 1.1 Information provided by the applicant regarding the volatilisation of iodine

In the iodine Assessment Report for PTs, 1, 3, 4 and 22 (Sweden 2013) it is clearly detailed in the identity chapter 2.1.1, that "In the case of iodophor 1 (iodine complexed with surfactants) […] iodine can be regarded as the active substance […] present in stabilized (complexed) form." Analogously, iodophor 2 (PVP-iodine) is described as a complex between iodine and PVP. In summary, both iodophors are regarded as carriers which are capable of complexing iodine in their scaffolds.

As the iodine dossier has been approved by all EU member states, it can be concluded that there is a common understanding about the fact that iodine used in PT 3 is complex-bound either to surfactants (in the case of iodophor 1) or PVP (in the case of PVP-iodine, i.e. iodophor 2).

Despite the clear description in the iodine dossier, more details on the structure of iodophors and the release of complex-bound iodine from these iodophors are included below.

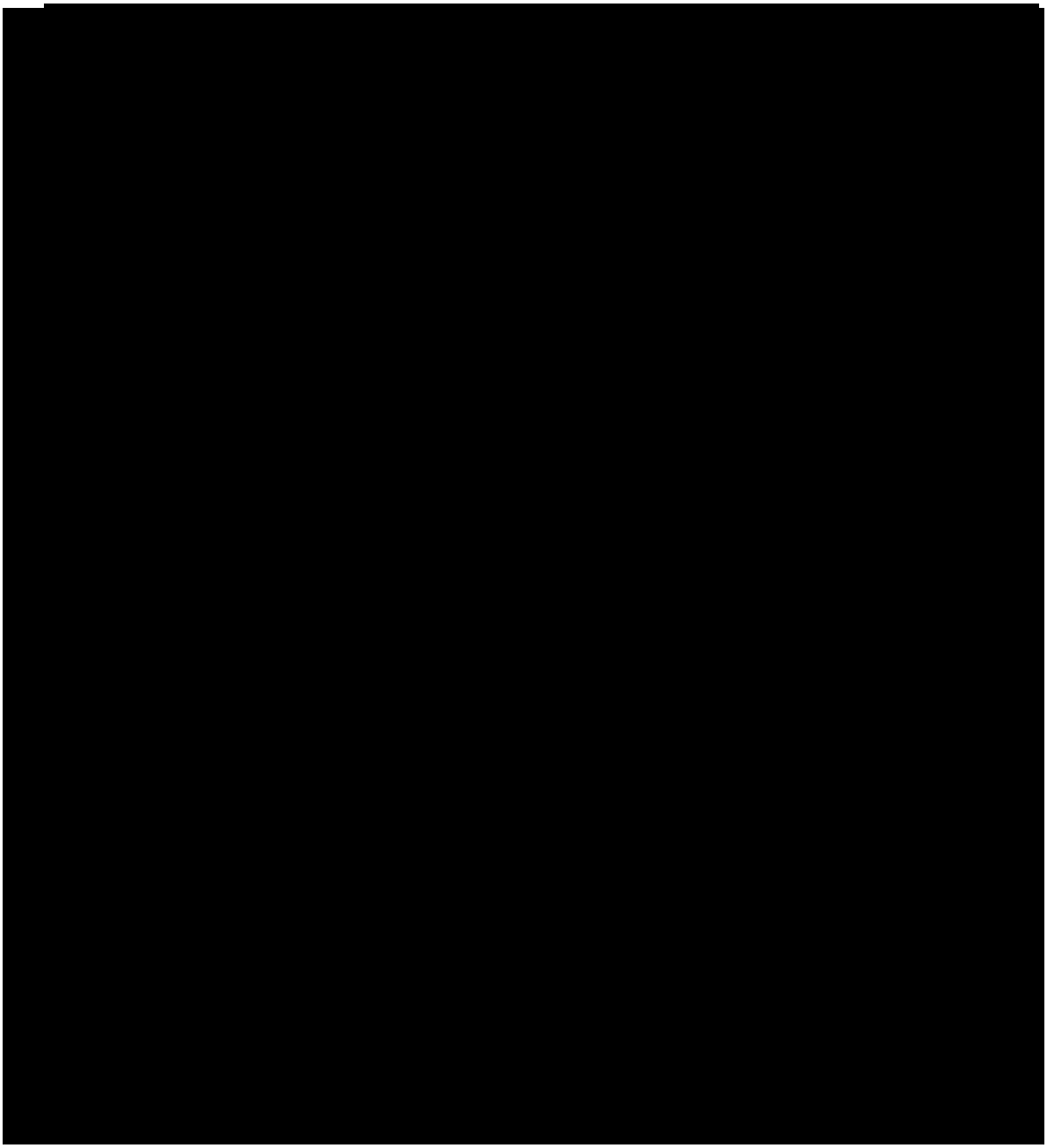
[redacted]

[redacted]

Available iodine (available I_2) = *iodine that can be titrated with sodium thiosulphate; also the complex bound iodine fraction can be determined*

Iodide (I^-) = *reaction partner of available iodine in the iodophor*

Triiodide (I_3^-) =	*iodine species bound in iodophor-complex, reaction product of I_2 and I^-*
Total iodine =	*sum of available iodine + iodide content*
Free iodine (free I_2) =	*non-complexed iodine that can be determined via dialysis or in an electrochemical model, microbial activity is proportional to the free iodine content*



Conclusion

Iodine used for teat disinfection in PT3 is complex-bound to iodophors in the form of triiodide (I_3^-).

In aqueous solutions, the bound triiodide releases only minute fractions of free (molecular) iodine (I_2).

Free iodine (I_2) immediately reacts with organic matter and forms ionic iodine species such as iodide (I^-) which do not tend to evaporate.
Residual free iodine (I_2) in aqueous solutions, if at all present, is considered to lead to negligible exposure towards iodine vapour.

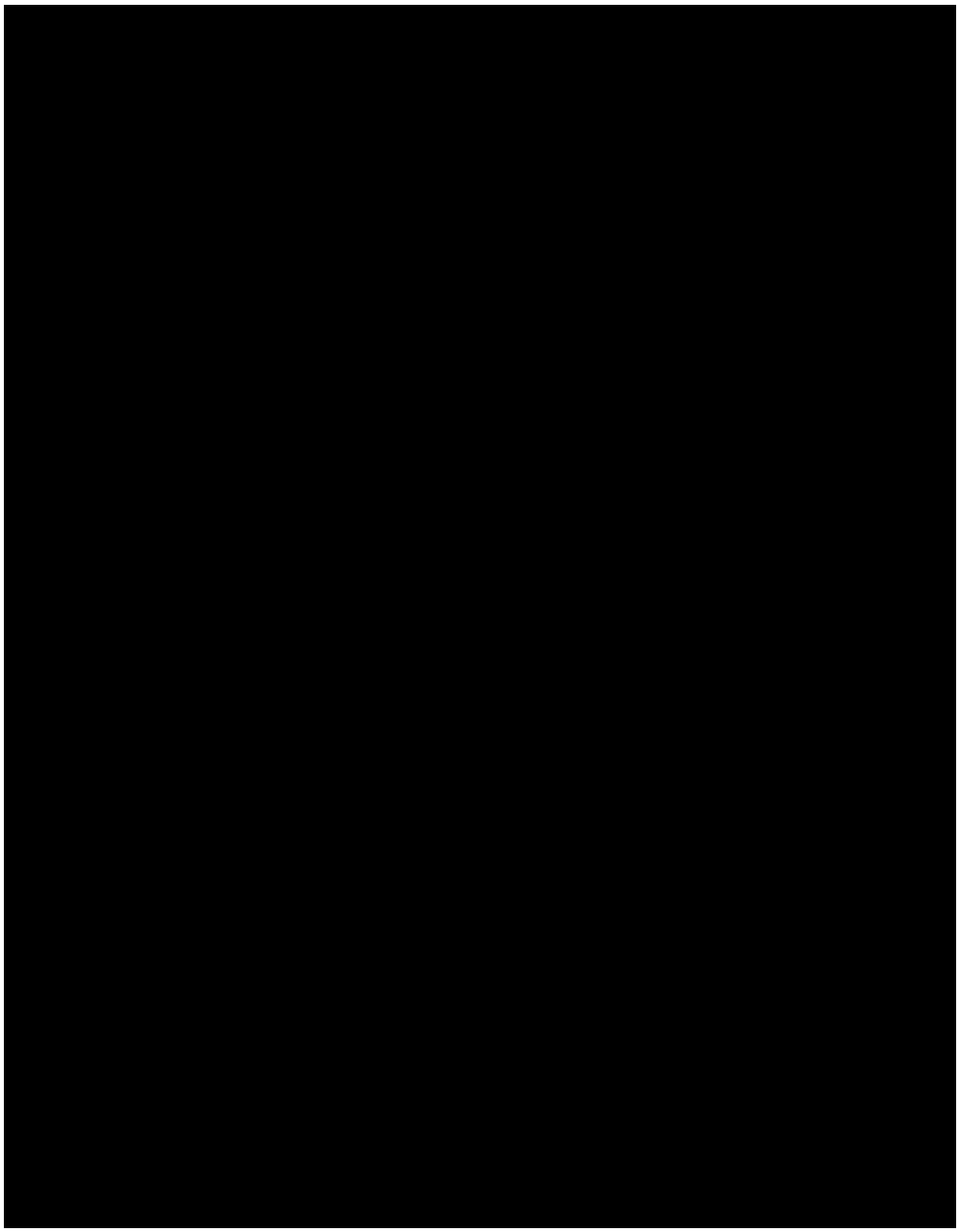


Figure 1.2. Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product through spraying for 55 minutes per day. No PPE.

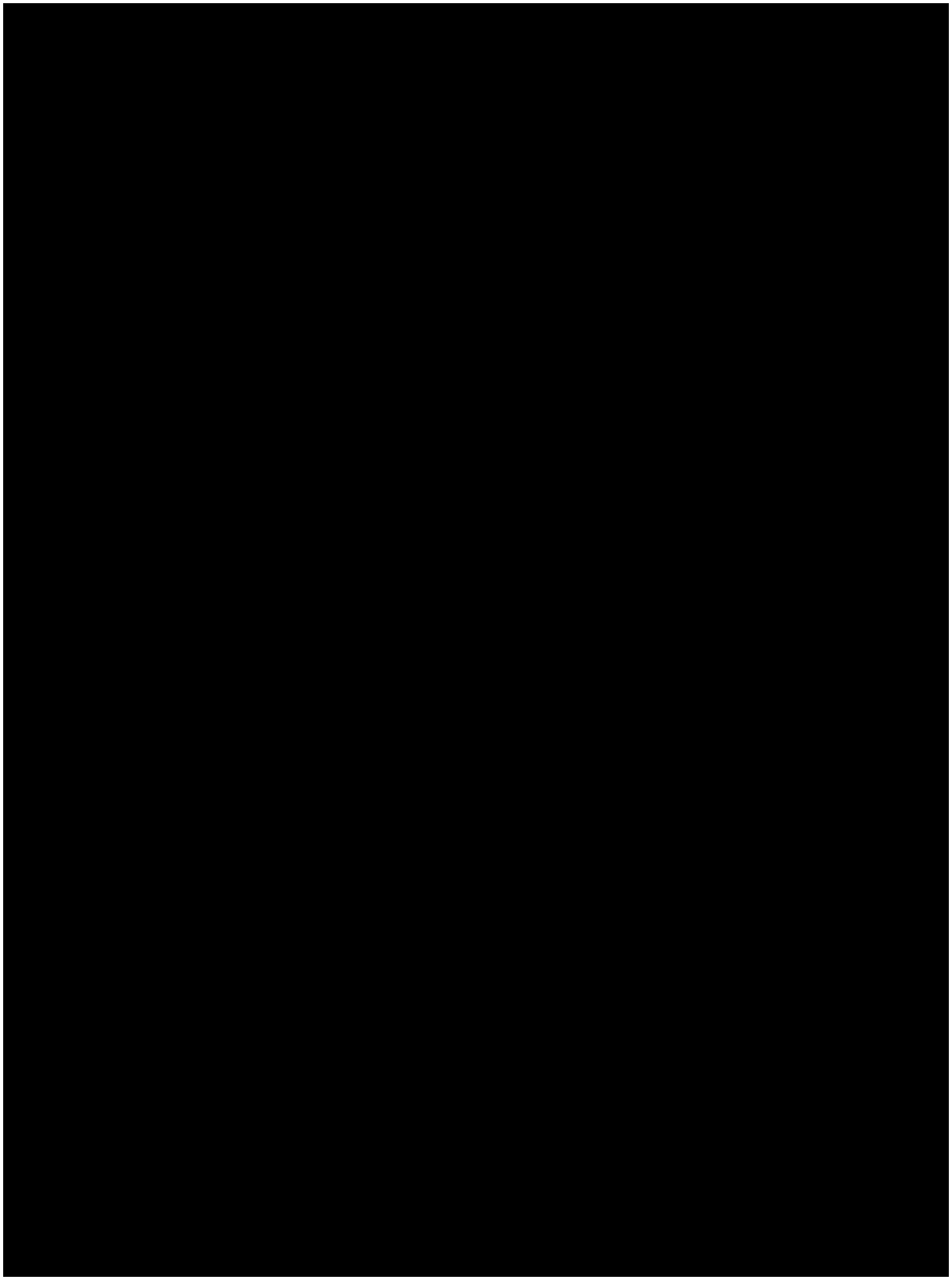


Figure 1.3. Scenario 3, Tier 1 assessment: primary exposure to total iodine for a professional user applying the product through spray equipment for 55 minutes per day. PPE: gloves.

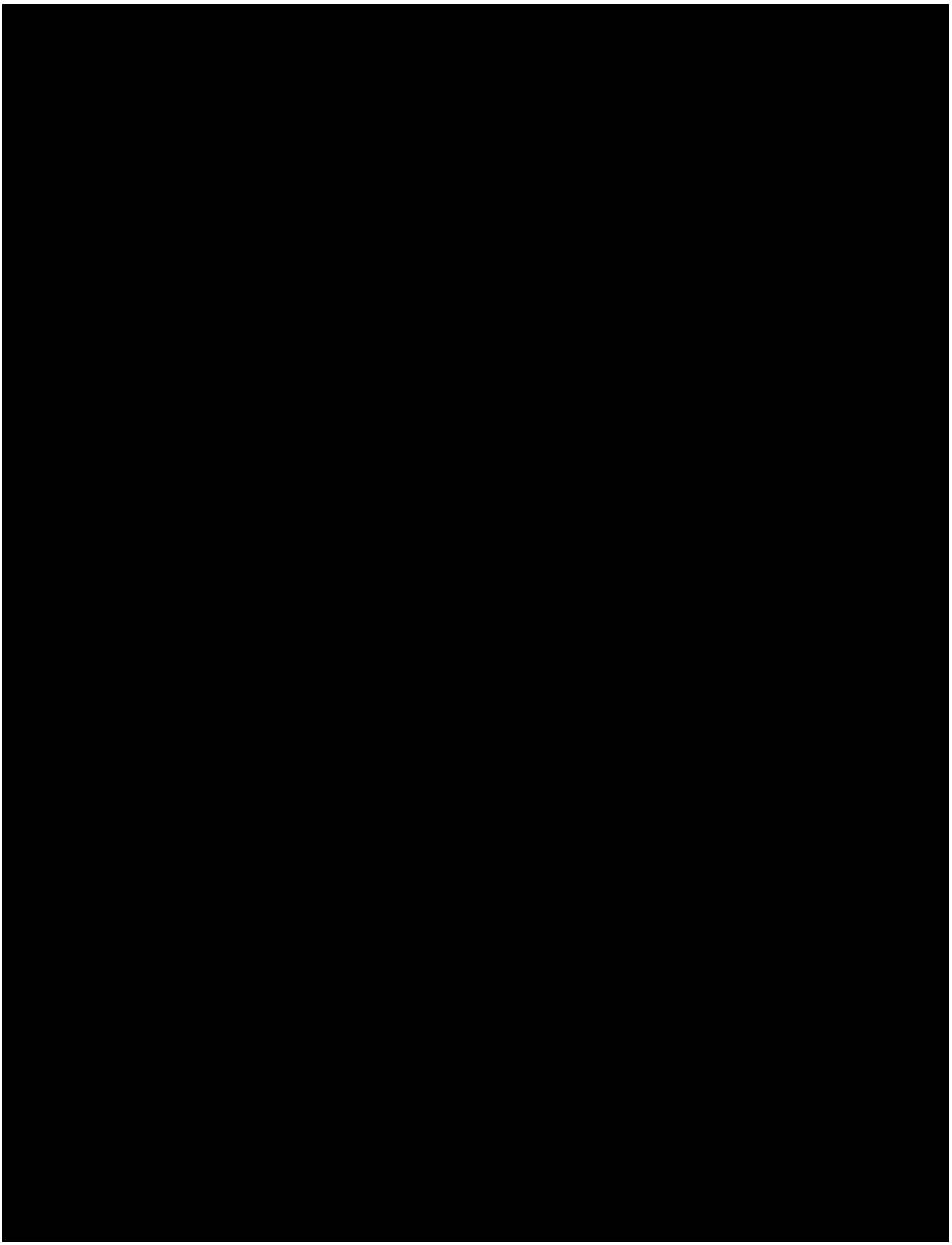


Figure 1.4. Scenario 3, Tier 1 assessment: primary exposure to total iodine for a professional user applying the product through spray equipment for 55 minutes per day. PPE: gloves and coated coveralls

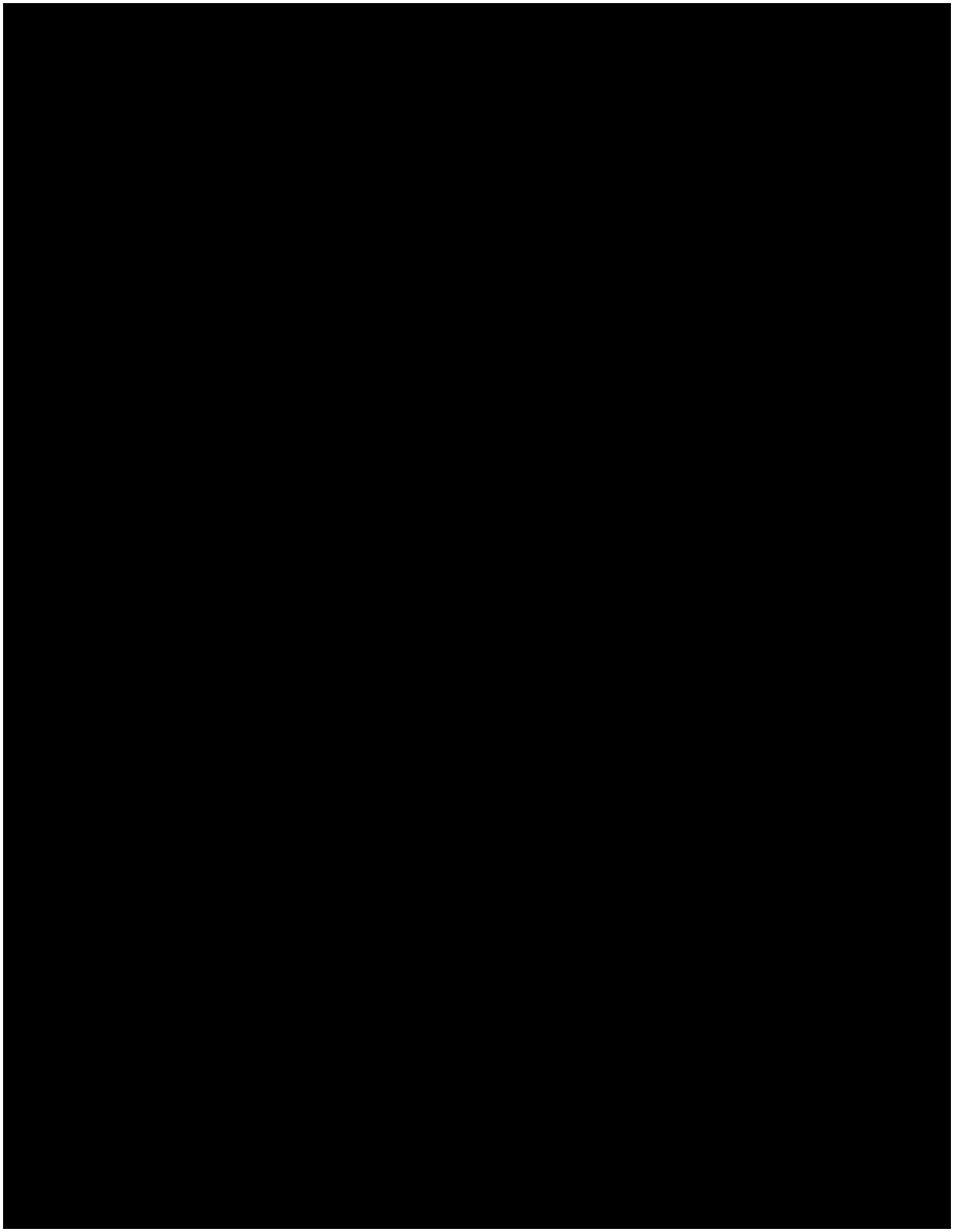


Figure 1.5. Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product through spraying for 27.5 minutes per day. No PPE.

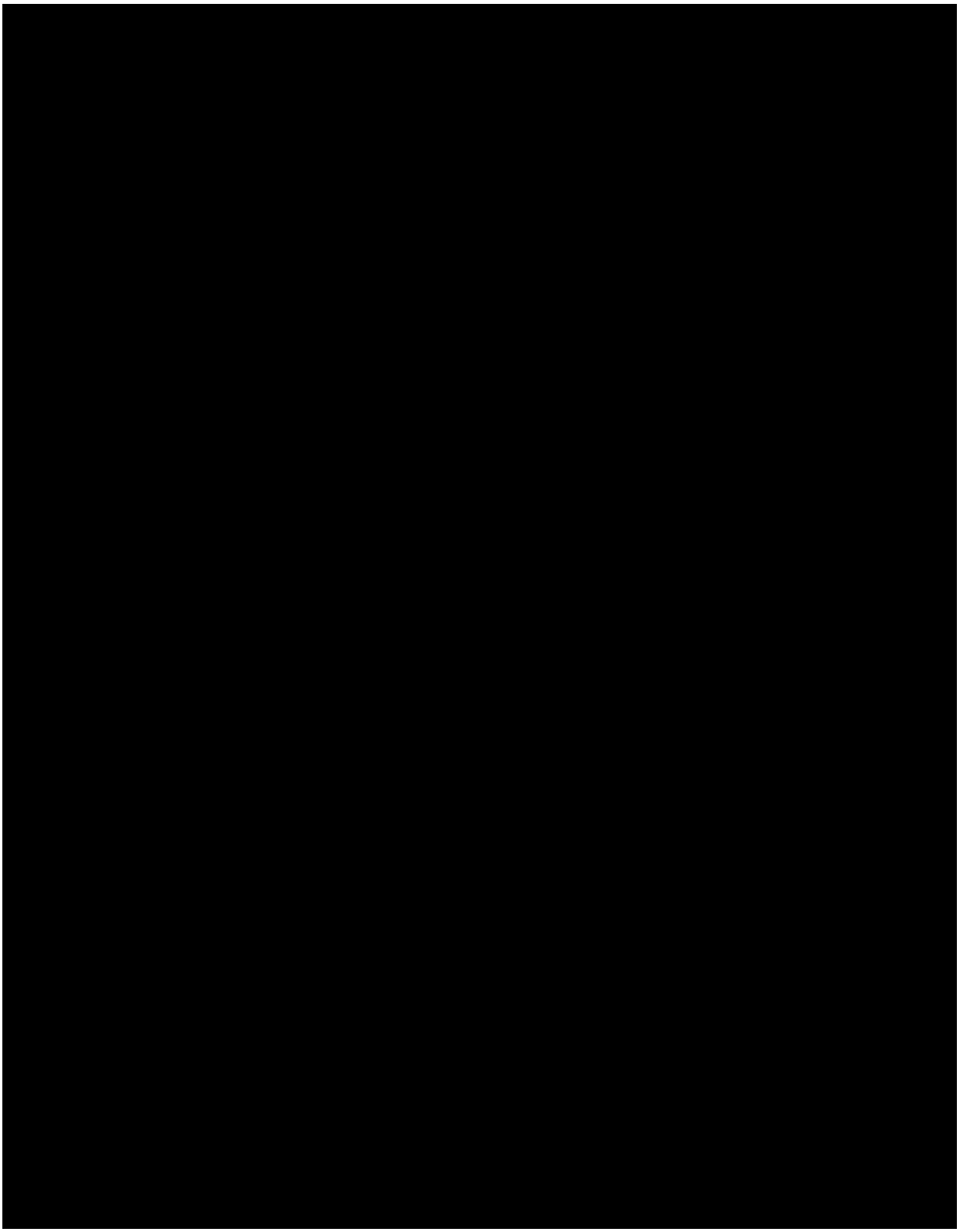
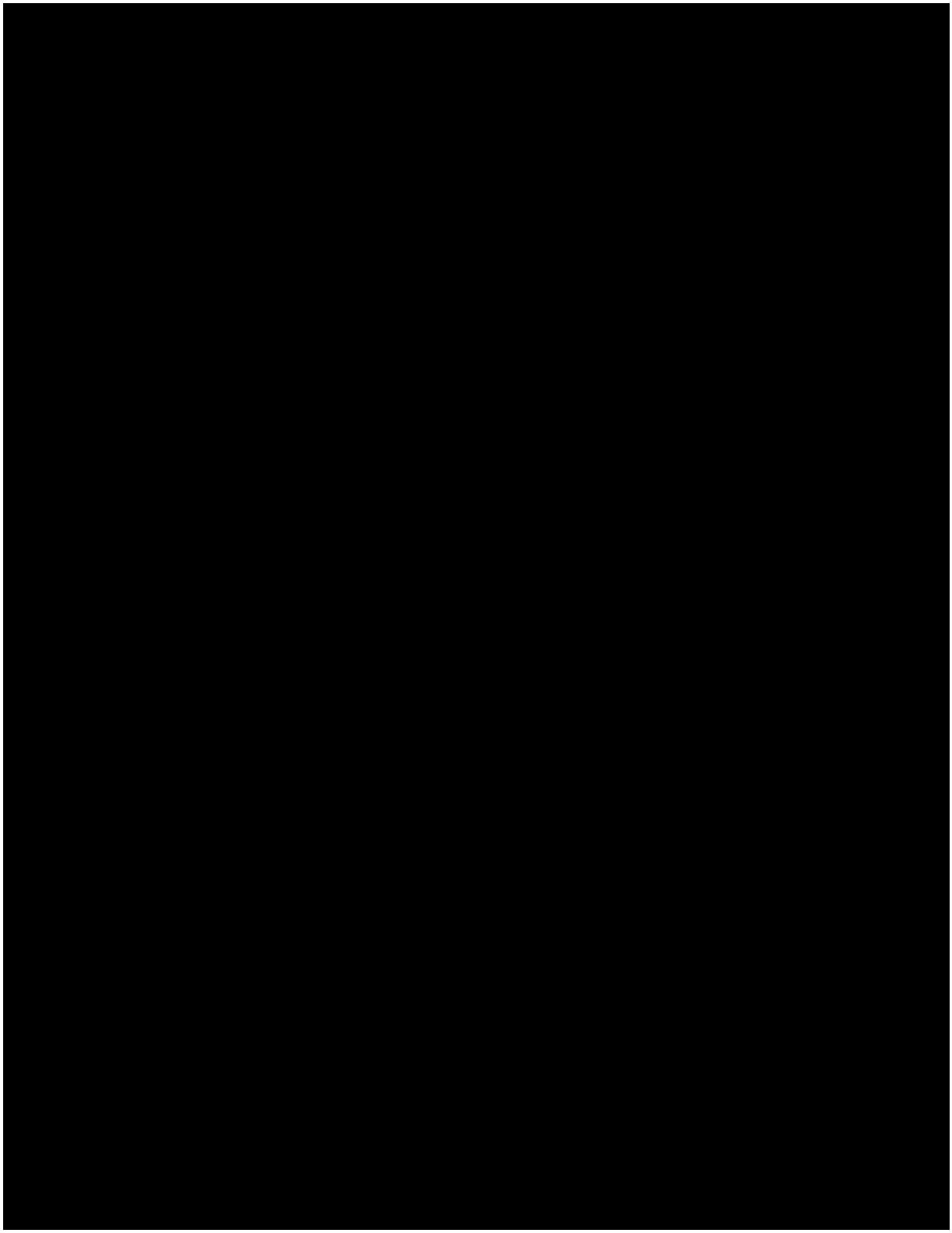
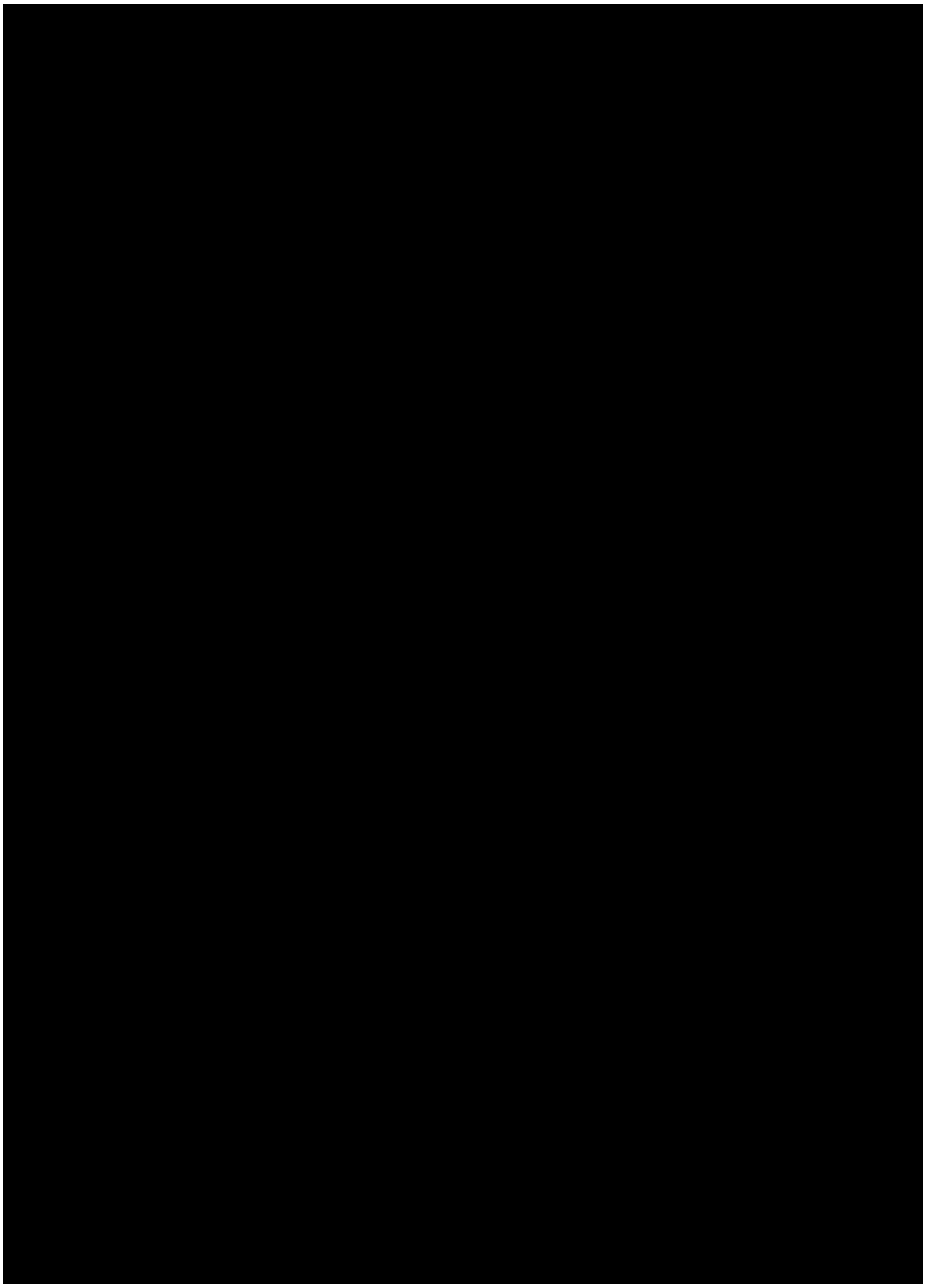
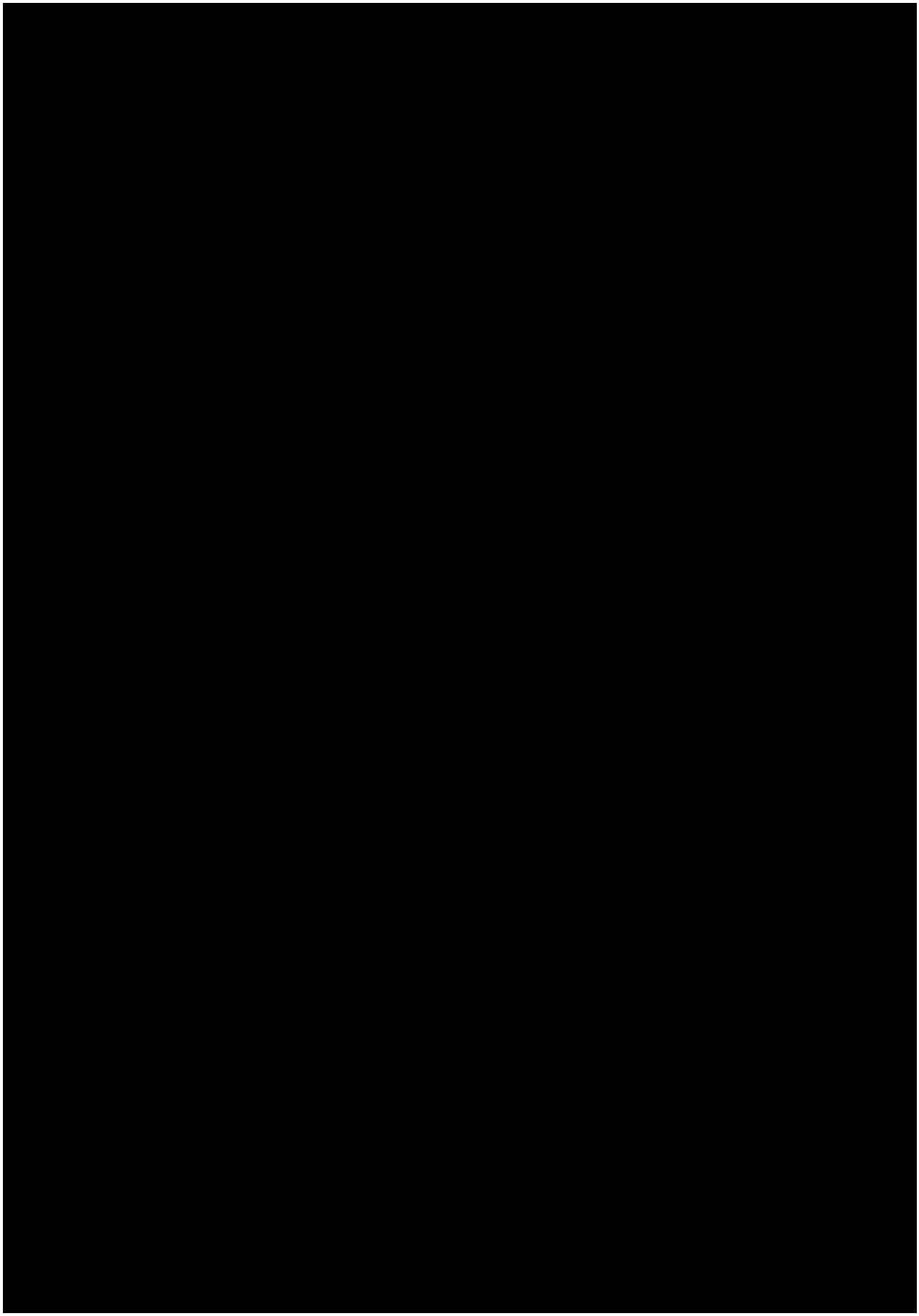


Figure 1.6. Scenario 3, Tier 1 assessment: primary exposure to iodine for a professional user applying the product through spraying for 27.5 minutes per day. PPE: gloves



Environmental Risk Assessment





3.3 Member State Confidential Annex

Please see R4BP3 asset

3.4 Confidential Annex

Please see R4BP3 asset