Summary of product characteristics for a biocidal product family

Family name: Deosan Activate BPF based on Iodine

Product type(s): PT03 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019228-0000

R4BP 3 asset reference number: IS-0020496-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

Deosan Activate BPF based on Iodine

1.2. Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder

Name	Diversey Europe Operations B.V.
Address	Regulatory team Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands

Authorisation number

EU-0019228-0000

R4BP 3 asset reference number

IS-0020496-0000

Date of the authorisation

03/04/2019

Expiry date of the authorisation

31/03/2029

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer	Diversey Europe Operations B.V.			
Address of the manufacturer	Maarssenbroeksedijk 2 3542 DN Utrecht Netherlands			
Location of manufacturing sites	Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy			
	Avenida Conde Duque 5, 7 y 9 Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain			
	Rembrandtlaan 414 7545 ZW Enschede Netherlands			
	Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom			
	Morschheimer Strasse 12 67292 Kirchheimbolanden Germany			

1.5. Manufacturer(s) of the active substance(s)

Active substance	1319 - Iodine
Name of the manufacturer	ACF Minera S.A.
Address of the manufacturer	San Martin No 499 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine 118 0000 Pozo Almonte Chile
Active substance	4040 Jadha
Notive substance	1319 - Iodine
Name of the manufacturer	Sociedad Quimica y Minera (SQM) S.A.
Name of the manufacturer	Sociedad Quimica y Minera (SQM) S.A.

Active substance	1319 - Iodine
Name of the manufacturer	Cosayach Nitratos S.A.
Address of the manufacturer	Hnos Amunátegui 178 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 118 0000 Pozo Almonte Chile
Active substance	1319 - Iodine
Name of the manufacturer	Nihon Tennen Gas Development Co., Ltd.
Address of the manufacturer	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 Chiba Japan
Active substance	1319 - Iodine
Active substance Name of the manufacturer	1319 - Iodine ISE Chemicals Corporation
Name of the manufacturer	ISE Chemicals Corporation
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	ISE Chemicals Corporation 3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan
Name of the manufacturer Address of the manufacturer	ISE Chemicals Corporation 3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	ISE Chemicals Corporation 3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan Shirasto Plant (3695 Kitaimaizumi, Oamishirasato City 299-3201 Chiba Japan
Name of the manufacturer Address of the manufacturer Location of manufacturing sites Active substance	ISE Chemicals Corporation 3-1, Kyobashi 1-Chome 104-0031 Tokyo Japan Shirasto Plant (3695 Kitaimaizumi, Oamishirasato City 299-3201 Chiba Japan 1319 - Iodine

2. Product family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 1,6

2.2. Type(s) of formulation	
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AL - Any other liquid

SL - Soluble concentrate

GW - Water soluble gel

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 1 - Deosan Activate BPF - Concentrate

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,35 - 1,6

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

SL - Soluble concentrate

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

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

Keep out of reach of children.

Avoid release to the environment.

Dispose of contents to in accordance with national regulations.

Dispose of container to in accordance with national regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual dipping

Detailed description:

Teat disinfectant, for direct application to lactating animals pre milking. Applied directly to animal teats pre milking via manual dipping method

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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.

Number and timing of application:

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)

4.1.1 Use-specific instructions for use

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

4.1.2 Use-specific risk mitiga	ation measures
See section 5 - General Directions for Us	Se
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See section 5 - General Directions for Us	Se
4.1.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	se
1.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product
See section 5 - General Directions for Us	
4.2 Use description	
Use 2 - Use # 2 Pre-milking disi	nfection, Manual foaming (concentrate)
Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:

Field(s) of use

Indoor

Indoor

Application method(s)

Method: Manual foaming Detailed description:

Teat disinfectant, for direct application to lactating animals pre milking Applied directly to animal teats pre milking via manual foaming method

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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.

Number and timing of application:

3 pre milking applications, per animal, per day

Apply a maximum of 5 ml/ 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)

4.2.1 Use-specific instructions for use

For products containing 1.5% iodine: 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 foaming application method.

3 pre-milking applications, per animal, per day

Apply a maximum of 5 ml product/ animal /application

4.2.2 Use-specific risk mitiga	ation measures
See section 5 - General Directions for Us	se
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See section 5 - General Directions for Us	se
4.2.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	se
4.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See section 5 - General Directions for Us	se e
4.3 Use description	
Use 3 - Use # 3 Pre-milking disi	nfection, Manual spraying (concentrate)
Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including	ı
development stage)	

Scientific name: Bacteria Common name: other Development stage:

Scientific name: Yeast Common name: yeast Development stage:

Field(s) of use

Indoor

Indoor

Application method(s)

Method: Manual spraying Detailed description:

Teat disinfectant, for direct application to lactating animals pre milking Applied directly to animal teats pre milking via manual spraying method.

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine Dilute1 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.

Number and timing of application:

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)

4.3.1 Use-specific instructions for use
For products containing 1.5% iodine: 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
4.3.2 Use-specific risk mitigation measures
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See section 5 - General Directions for Use
4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See section 5 - General Directions for Use
4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See section 5 - General Directions for Use		
4.4 Use description		
Use 4 - Use # 4 Post-milking dis	infection, Manual dipping (concentrate)	
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:	
	Scientific name: Yeast Common name: yeast Development stage:	
Field(s) of use	Indoor	
	indoor	
Application method(s)	Method: Manual dipping Detailed description:	
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual dipping method.	
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application:	
	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)	
4.4.1 Use-specific instruction	ns for use	
Applied directly to animal teats post milking via manual dipping method. For products containing 1.5% iodine: 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 (5 applications in total) Apply a maximum of 10 ml product/ animal /application		
4.4.2 Use-specific risk mitiga	ition measures	
See section 5 - General Directions for Us	se	
-	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
See section 5 - General Directions for Us	se	

Professional

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

See section 5 - General Directions for Use 4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See section 5 - General Directions for Use 4.5 Use description Use 5 - Use # 5 Post-milking disinfection, Manual foaming (concentrate) PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: other Target organism(s) (including development stage) Development stage: Scientific name: Yeast Common name: yeast Development stage: Indoor Field(s) of use Indoor Method: Manual foaming Application method(s) Detailed description: Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual foaming method.

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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.

Number and timing of application:

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)

4.5.1 Use-specific instructions for use

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

For products containing 1.5% iodine: 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

4.5.2 Use-specific risk mitigation measures

See section 5 - General Directions for Use		
<u> </u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
See section 5 - General Directions for Us	se	
4.5.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its	
See section 5 - General Directions for Us	se	
1.5.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage	
See section 5 - General Directions for Us	se	
4.6 Use description		
Use 6 - Use # 6 Post-milking dis	sinfection, Manual spraying (concentrate)	
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:	
	Scientific name: Yeast Common name: yeast Development stage:	

Field(s) of use

	Indoor
	Indoor
Application method(s)	Method: Manual spraying Detailed description:
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual spraying method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application: 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)

4.6.1 Use-specific instructions for use

Applied directly to animal teats post milking via manual spraying method. For products containing 1.5% iodine: 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
4.6.2 Use-specific risk mitigation measures
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
instructions and emergency measures to protect the environment
See section 5 - General Directions for Use
4.6.4 Where specific to the use, the instructions for safe disposal of the product and its backaging
See section 5 - General Directions for Use

4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage		
See section 5 - General Directions for Use		
4.7 Use description		
Use 7 - Use # 7 Post-milking disinfection, Automatic spraying (concentrate)		
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:	
	Scientific name: Yeast Common name: yeast Development stage:	
Field(s) of use	Indoor	
	Indoor	
Application method(s)	Method: Automatic spraying Detailed description:	
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via automatic spraying method.	
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application:	

	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	
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)	
4.7.1 Use-specific instruction	ns for use	
Applied directly to animal teats post milking via automatic spraying method. For products containing 1.5% iodine: 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, p Apply a maximum of 15 ml product/ anim	er day. Not to be combined with lodine based pre-milking disinfection.	
4.7.2 Use-specific risk mitigation measures		
See section 5 - General Directions for Use		

4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment		
See section 5 - General Directions for Us	6e	
4.7.4 Where specific to the uspackaging	se, the instructions for safe disposal of the product and its	
See section 5 - General Directions for Us	se	
4.7.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product	
See section 5 - General Directions for Us	·	
4.8 Use description		
Use 8 - Use # 8 Post-milking dis	sinfection, Semi-automatic dipping (concentrate)	
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:	
	Scientific name: Yeast Common name: yeast Development stage:	
Field(s) of use	Indoor	
	Indoor	

Application method(s)	Method: Semi-automatic dipping Detailed description: Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via semi-automatic dipping method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application: 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)

4.8.1 Use-specific instructions for use

Applied directly to animal teats post milking For products containing 1.5% iodine: Diltiproducts with another concentration this 3 post milking applications, per animal, papply a maximum of 10 ml product/ animal product/	ute 1 part of product to 4 parts water to achieve 0.3% in use Iodine concentration. For instruction should be adapted. per day	
4.8.2 Use-specific risk mitiga	ation measures	
See section 5 - General Directions for Us	Se Se	
-	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
See section 5 - General Directions for Us	Se Se	
4.8.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its	
See section 5 - General Directions for Us	se Se	
4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage		
See section 5 - General Directions for Use		
4.9 Use description		
Use 9 - Use # 9 Pre and post-milking disinfection, manual dipping (concentrate)		
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	

Target organism(s)	(including
development stage	!)

Scientific name: bacteria Common name: other Development stage:

Scientific name: Yeast Common name: yeast Development stage:

Field(s) of use

Indoor

Indoor

Application method(s)

Method: Manual dipping Detailed description:

Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual dipping method

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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.

Number and timing of application:

3 pre 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)

4.9.1 Use-specific instructions for use

For products containing 1.5% iodine: 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 and post milking via manual dipping method. 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 10 ml product/ animal /application
4.9.2 Use-specific risk mitigation measures
See section 5 - General Directions for Use
4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See section 5 - General Directions for Use
4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See section 5 - General Directions for Use
1.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See section 5 - General Directions for Use
4.10 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual foaming Detailed description: Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual foaming method
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application: 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 5 ml/ 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)

4.10.1 Use-specific instructions for use

For products containing 1.5% iodine: 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 and post milking via manual foaming application method. 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total) Apply a maximum of 5 ml product/ animal /application
4.10.2 Use-specific risk mitigation measures
See section 5 - General Directions for Use
4.10.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment
See section 5 - General Directions for Use
4.10.4 Where specific to the use, the instructions for safe disposal of the product and its packaging
See section 5 - General Directions for Use
1.10.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage
See section 5 - General Directions for Use
4.11 Use description

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

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual spraying Detailed description:
	Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual spraying method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): For products containing 1.5% iodine: 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. Number and timing of application: 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

	950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)
4.11.1 Use-specific instruction	ons for use
	ute 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. Ost milking via manual spraying application method.
	er animal, per day (up to 5 applications in total)
Apply a maximum of 15 ml product/ anir	
4.11.2 Use-specific risk mitig	gation measures
	es during product handling phase (glove material to be specified by the authorisation holder
within the product information) Wear suitable protective footwear (EN 1	.3832) when applying the product.
A protective coverall (at least type 6, EN	
<u>-</u>	use, the particulars of likely direct or indirect effects, first aid
instructions and emergency	measures to protect the environment
See section 5 - General Directions for U	se
4.11.4 Where specific to the	use, the instructions for safe disposal of the product and its
packaging	·
One continue 5 One 150 iii ii iii	
See section 5 - General Directions for U	Se Se

200 litre HDPE or f-HDPE drum

See section 5 - 0	General Directions for Use
Comercia	divertions for use of the mosts CDC
o. Generai (directions for use of the meta SPC
5.1. Instructi	ions for use
Jiri matraot	
The product mus	st be brought to temperature >20°C before use
Pre milking:	st be brought to temperature >20 C before use
Apply product to	full length of each teat.
	e against bacteria and yeast, product must be left in contact with the skin for at least 30 seconds. riate contact time, thoroughly remove the product, using a single service paper towel/cloth to ensure teats are clean
and dry.	ncentration of 3000mg/Kg (0.3% w/w)
	icentiation of 3000mg/kg (0.3% w/w)
Post milking: Cover the full ler	ngth of each teat with the product, immediately after milking.
	ent contact time, care should be taken that the product is not removed after application (e.g. keep the cows standin
	ncentration of 3000mg/Kg (0.3% w/w)
5.2. Risk mit	igation measures
This product can	be used for pre- and post-milking disinfection in combination (up to 5 applications in total per animal per day).
	ald not be used in combination with a different iodine-based product.
The use of a dos	sing pump for filling the product into the application equipment is recommended.

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.

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.

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.

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 Do not store at temperatures above 40°C Shelf life 24 months

6. Other information

The hazard and precautionary statements shall be in Icelandic on the label.

The hazard statements in Icelandic:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

The precautionary statements in Icelandic:

P101 Ef leita þarf læknis skal hafa ílát eða merkimiða tiltæk.

P102 Geymist þar sem börn ná ekki til.

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi í samræmi við landsbundnar reglur.

P501 Fargið íláti í samræmi við landsbundnar reglur.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Deosan Activate Pre AG106	Market area: EU
	Deosan Activate Pre	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IS-0020496-0001 1-1	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,5

Trade name(s)

Deosan Activate Pre/Post Conc. AG218	Market area: EU
Deosan Activate Pre/Post Conc.	Market area: EU
Deosan Hitech concentrate	Market area: EU
Deosan Activate Pre/Post Plus Conc. AG218	Market area: EU
Deosan Activate Pre/Post Plus Conc.	Market area: EU
Iodine Concentrate	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0020496-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,5

Trade name(s)

Deosan Activate Pro	Market area: EU
Iodine Concentrate Plus	Market area: EU
Iodine Concentrate Pro	Market area: EU

Deosan Activate Pro AG225	Market area: EU
IS-0020496-0007 1-1	

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	1,5

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 2 - Deosan Activate BPF – RTU liquid

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1.Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 0,32

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

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

Keep out of reach of children.

Avoid release to the environment.

Dispose of contents to in accordance with national regulations.

Dispose of container to in accordance with national regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 12 Pre-milking disinfection, manual dipping (RTU liquid)

_				
Pr	od	uct	tv	pe

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: other Development stage:

Scientific name: Yeast Common name: other Development stage:

Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual dipping Detailed description:
	Teat disinfectant, for direct application to lactating animals pre milking
	Applied directly to animal teats pre-milking via manual dipping methods
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
	Number and timing of application:
	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)

4.1.1 Use-specific instructions for use

·				
Applied directly to animal teats pre-milking via manual dipping methods. Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. 3 pre-milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application				
4.1.2 Use-specific risk mitiga	tion measures			
See section 5 - General Directions for Us	e			
4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment				
See section 5 - General Directions for Us	е			
4.1.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its			
See section 5 - General Directions for Use				
1.1.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage			
See section 5 - General Directions for Use				
4.2 Use description Use 2 - Use # 13 – Pre-milking disinfection, manual foaming (RTU liquid)				
Product type	PT03 - Veterinary hygiene (Disinfectants)			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:			
	Scientific name: Yeast Common name: yeast Development stage:			

Field(s) of use	Indoor
Application method(s)	Method: Manual foaming Detailed description: Teat disinfectant, for direct application to lactating animals pre milking Applied directly to animal teats pre-milking via manual foaming method.
Application rate(s) and frequencies	Application Rate: In use lodine concentration of 3000 mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. Number and timing of application: 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)

4.2.1 Use-specific instructions for use

Ready to use formulation containing 0.3% w/w lodine. 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		
4.2.2 Use-specific risk mitiga	tion measures	
See section 5 - General Directions for Us	е	
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
See section 5 - General Directions for Use		
4.2.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its	
See section 5 - General Directions for Us	е	
1.2.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage	
See section 5 - General Directions for Use		
4.3 Use description		
Use 3 - Use # 14 Pre-milking disinfection, manual spraying (RTU liquid)		
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised	-	

use

Target organism(s) (including development stage)

Scientific name: Bacteria Common name: other Development stage:

Scientific name: Yeast Common name: yeast Development stage:

Field(s) of use

Indoor

indoor

Application method(s)

Method: Manual spraying Detailed description:

Teat disinfectant, for direct application to lactating animals pre milking

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

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000 mg/Kg (0.3% w/w)

Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before

Number and timing of application:

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)

4.3.1 Use-specific instruction	ns for use
Applied directly to animal teats pre-milkin Ready to use formulation containing 0.3% 3 pre-milking applications, per animal, pe Apply a maximum of 15 ml product/anima	6 w/w lodine. Do not dilute before use. or day.
4.3.2 Use-specific risk mitiga	tion measures
Wear protective chemical resistant gloves within the product information)	s during product handling phase (glove material to be specified by the authorisation holder
	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See section 5 - General Directions for Us	е
4.3.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	е
_	
4.3.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product torage
See section 5 - General Directions for Us	e e

4.4 Use description

Use 4 - Use # 15 - Post-milking disinfection, manual dipping (RTU liquid)

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
ricia(s) or use	Indoor
Application method(s)	Method: Manual dipping Detailed description:
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual dipping method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
	Number and timing of application: 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	

	200 litre HDPE or f-HDPE drum
	950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)
4.4.1 Use-specific instruction	ns for use
Applied directly to animal teats post milkin Ready to use formulation containing 0.3% 3 post milking applications, per animal, p Apply a maximum of 10 ml product/anima	6 w/w lodine. Do not dilute before use. er day.
4.4.2 Use-specific risk mitiga	tion measures
See section 5 - General Directions for Us	е
=	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See section 5 - General Directions for Us	е
4.4.4 Where specific to the us packaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	е

1, 5 & 20 litre HDPE or f-HDPE canister

-	4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage		
See section 5 - General Directions for Us	se		
4.5 Use description			
Use 5 - Use # 16 - Post-milking	disinfection, manual foaming (RTU liquid)		
Product type	PT03 - Veterinary hygiene (Disinfectants)		
Where relevant, an exact description of the authorised use	-		
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:		
	Scientific name: Yeast Common name: yeast Development stage:		
Field(s) of use	Indoor		
	Indoor		
Application method(s)	Method: Manual foaming Detailed description:		
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual foaming method.		
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000 mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. Number and timing of application:		

	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)
4.5.1 Use-specific instruction	ns for use
Applied directly to animal teats post milki	ng via manual foaming method.)
Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. 3 post milking applications, per animal, per day. Apply a maximum of 5 ml product/ animal /application	
4.5.2 Use-specific risk mitiga	ition measures
See section 5 - General Directions for Use	
4 E 2 Whore openific to the	se, the particulars of likely direct or indirect effects, first aid

instructions and emergency measures to protect the environment

SUMMARY OF PRODUCT CHARACTERISTICS

See section 5 - General Directions for Us	se
4.5.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	se
	se, the conditions of storage and shelf-life of the product
under normal conditions of s	
See section 5 - General Directions for Us	Se Control of the Con
4.6 Use description	
Use 6 - Use # 17 - Post-milking	disinfection, manual spraying (RTU liquid)
Droduct type	PT03 - Veterinary hygiene (Disinfectants)
Product type	
Where relevant, an exact description of the authorised	-
use	
Target organism(s) (including	Scientific name: Bacteria Common name: other
development stage)	Development stage:
	Scientific name: Yeast Common name: yeast Device name: Yeast
	Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual spraying Detailed description:
	Teat disinfectant, for direct application to lactating animals post milking
	Applied directly to animal teats post milking via manual spraying method.

Application rate(s) and frequencies

Application Rate: In use Iodine concentration of 3000 mg/Kg (0.3% w/w)

Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before

Number and timing of application:

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)

4.6.1 Use-specific instructions for use

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

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

3 post milking applications, per animal, per day.

Apply a maximum of 15 ml product/ animal /application

4.6.2 Use-specific risk mitigation measures

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

	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment	
See section 5 - General Directions for Us	se	
4.6.4 Where specific to the u packaging	se, the instructions for safe disposal of the product and its	
See section 5 - General Directions for Us	se	
4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See section 5 - General Directions for Use		
4.7 Use description		
·		
Use 7 - Use # 18 – Post-milking milking disinfection (RTU liquid	disinfection, automatic spraying (not to be combined with a pre-	
Product type	PT03 - Veterinary hygiene (Disinfectants)	
Where relevant, an exact description of the authorised use	-	
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:	
	Scientific name: Yeast Common name: yeast Development stage:	
	Indoor	
Field(s) of use		
	Indoor	

Application method(s)	Method: Automatic spraying Detailed description:	
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via automatic spraying method.	
Application rate(s) and frequencies	Application Rate: In use lodine concentration of 3000 mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. Number and timing of application:	
	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)	

4.7.1 Use-specific instructions for use

Applied directly to animal teats post milking via automatic spraying method. Ready to use formulation containing 0.3% w/w lodine. 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 4.7.2 Use-specific risk mitigation measures See section 5 - General Directions for Use 4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment See section 5 - General Directions for Use 4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging See section 5 - General Directions for Use 4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See section 5 - General Directions for Use 4.8 Use description Use 8 - Use # 19 - Post-milking disinfection, semi-automatic dipping (RTU liquid) PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact description of the authorised Scientific name: Bacteria Target organism(s) (including Common name: other Development stage: development stage) Scientific name: Yeast Common name: yeast Development stage:

Field(s) of use

	Indoor
	Indoor
Application method(s)	Method: Semi-automatic dipping Detailed description:
., ,,	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via semi-automatic dipping method.
	Applied directly to animal teats post milking via semi-automatic dippling method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use.
	Number and timing of application:
	3 post milking applications per animal, per day. Apply a maximum of 10 ml product/ animal / application
Category(ies) of users	Professional
Category(les) of users	
Pack sizes and packaging material	4. F. 0. 00 litra LIDDE on CUDDE positions
	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)

4.8.1 Use-specific instructions for use

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

4.8.2 Use-specific risk mitigation measures

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

4.9 Use description

Use 9 - Use # 20 - Pre and post milking disinfection, manual dipping (RTU liquid)

Product type

Where relevant, an exact description of the authorised use

Target organism(s) (including development stage)

PT03 - Veterinary hygiene (Disinfectants)

Scientific name: Bacteria Common name: other Development stage:

Scientific name: Yeast Common name: yeast

	Development stage:	
Field(s) of use	Indoor	
	Indoor	
Application method(s)	Method: Manual dipping Detailed description:	
	Teat disinfectant, for direct application to lactating animals pre and post milking	
	Applied directly to animal teats pre and post milking via manual dipping methods	
Application rate(s) and	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before	
frequencies	use. Number and timing of application:	
	3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total). Apply a maximum of 10 ml product/ animal /application	
	Professional	
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	
	200 III CHIBI E GIANI	
	950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)	

4.9.1 Use-specific instructions for use

Applied directly to animal teats pre-milkir Ready to use formulation containing 0.39 3 pre and 3 post milking applications, per Apply a maximum of 10 ml product/ anim	% w/w lodine. Do not dilute before use. r animal, per day (up to 5 applications in total).
4.9.2 Use-specific risk mitiga	ation measures
Wear protective chemical resistant glove within the product information)	es during product handling phase (glove material to be specified by the authorisation holder
<u>-</u>	se, the particulars of likely direct or indirect effects, first aid measures to protect the environment
See section 5 - General Directions for Us	3e
4.9.4 Where specific to the upackaging	se, the instructions for safe disposal of the product and its
See section 5 - General Directions for Us	Se
4.9.5 Where specific to the us under normal conditions of s	se, the conditions of storage and shelf-life of the product storage
See section 5 - General Directions for Us	se
4.10 Use description	
Use 10 - Use # 21 – Pre and pos	st milking disinfection, manual foaming (RTU liquid)
Product type	PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: other Development stage: Target organism(s) (including development stage) Scientific name: Yeast Common name: yeast Development stage: Indoor Field(s) of use Indoor Method: Manual foaming Application method(s) Detailed description: Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual foaming method. Application Rate: In use Iodine concentration of 3000 mg/Kg (0.3% w/w) Application rate(s) and Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before frequencies Number and timing of application: 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total). Apply a maximum of 5 ml product/ animal / application Professional Category(ies) of users 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)

4.10.1 Use-specific instructions for use
Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. Apply directly to animal teats pre and post milking via manual foaming application method. 3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total). Apply a maximum of 5 ml product/ animal /application
1.10.2 Use-specific risk mitigation measures
Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)
I.10.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
See section 5 - General Directions for Use
1.10.4 Where specific to the use, the instructions for safe disposal of the product and its backaging
See section 5 - General Directions for Use
.10.5 Where specific to the use, the conditions of storage and shelf-life of the product inder normal conditions of storage

See	section	5 -	General	Directions	for	Use

4.11 Use description

Use 11 - Use # 22 - Pre and nos	st milking disinfection, manual spraying (RTU liquid)
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Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	indoor
Application method(s)	Method: Manual spraying Detailed description:
	Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual spraying method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000 mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. Number and timing of application:
	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)

4.11.1 Use-specific instructions for use

Applied directly to animal teats pre and post milking via manual spraying method. Ready to use formulation containing 0.3% w/w lodine. 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

4.11.2 Use-specific risk mitigation measures

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

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

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use
I.11.5 Where specific to the use, the conditions of storage and shelf-life of the product
under normal conditions of storage
See section 5 - General Directions for Use
5. General directions for use of the meta SPC
5.1. Instructions for use
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 test with the product immediately after 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) In use Iodine concentration of 3000mg/Kg (0.3% w/w)
in use found concentration of socionig/Kg (0.570 w/w)
5.2. Risk mitigation measures
This product can be used for pre- and post-milking disinfection in combination (up to 5 applications in total per animal per day).
However, it should not be used in combination with a different iodine-based product.
The use of a dosing pump for filling the product into the application equipment is recommended.

. Particulars of likely direct or indirect effects, first aid instruceasures to protect the environment	tions and emergency
nalation: No known effects or symptoms in normal use. in contact: No known effects or symptoms in normal use. e contact: No known effects or symptoms in normal use. pestion: No known effects or symptoms in normal use	
er inhalation: Supply fresh air; consult doctor in case of symptoms. er skin contact: Instantly wash with water and soap and rinse thoroughly. er eye contact: Rinse opened eye for several minutes under running water (at least 15 minu er swallowing: Rinse out mouth and then drink plenty of water. Instantly call for doctor.	ites).
nedical advice is needed, have product container or label at hand ability and reactivity: activity: No reactivity hazards known under normal storage and use conditions. emical stability: Stable under normal storage and use conditions. ssibility of hazardous reactions: No hazardous reactions known under normal storage and use conditions. nditions to avoid: None known under normal storage and use conditions.	ise conditions.
izardous decomposition products: None known under normal storage and use conditions. Invironmental precautions: It is not to collect larger liquid spills. It is not and/or absorb spill with inert material, then place in suitable container.	
event run-off from entering drains, sewers or waterways. Ilect in closed and suitable containers for disposal. In not place spilled materials back into the original container.	
1. Instructions for safe disposal of the product and its packagin	ng
npty containers must be tripled rinsed prior to disposal uper towels used to dry animal teats and remove the product from them should be disposed onot discharge undiluted product to sewers.	of as normal/domestic waste.
. Conditions of storage and shelf-life of the product under nor	mal conditions of storag
ore only in original, placed container	

5

Store only in original, closed container Protect from frost Do not store at temperatures above 30°C Shelf life 24 months

6. Other information

The hazard and precautionary statements shall be in Icelandic on the label.

The hazard statements in Icelandic:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

The precautionary statements in Icelandic:

P101 Ef leita þarf læknis skal hafa ílát eða merkimiða tiltæk.

P102 Geymist þar sem börn ná ekki til.

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi í samræmi við landsbundnar reglur.

P501 Fargið íláti í samræmi við landsbundnar reglur.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	Deosan Activate Pre RTU AG108	Market area: EU
	Deosan Activate Pre RTU	Market area: EU
Authorisation number (R4BP 3 asset reference number - National Authorisation)	IS-0020496-0003 1-2	

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3

Trade name(s)

Deosan Activate Pre/Post AG217	Market area: EU
Deosan Activate Pre/Post	Market area: EU
Iodine Plus Pre & Post	Market area: EU
Deosan D4T Super AG211	Market area: EU
Agros Iodo	Market area: EU
Agros Iodo Multi	Market area: EU
Poviclyn liquido	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0020496-0004 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3

Trade name(s)

Deosan Activate PVP Plus AG215	Market area: EU
Deosan Activate PVP Plus	Market area: EU
Agros Iodo-Prev POS-Ordenha	Market area: EU
Deosan Hitech 2 AG214	Market area: EU
lodine Teat Dip Solution	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0020496-0005 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3

1. Meta SPC administrative information

1.1. Meta SPC identifier

Meta SPC 3 - Deosan Activate BPF - RTU gel

1.2. Suffix to the authorisation number

1-3

1.3 Product type(s)

PT03 - Veterinary hygiene (Disinfectants)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3 - 0,32

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

GW - Water soluble gel

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Harmful to aquatic life with long lasting effects.

Precautionary statements

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

Keep out of reach of children.

Avoid release to the environment.

Dispose of contents to in accordance with national regulations.

Dispose of container to in accordance with national regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Use # 23 - Pre-milking disinfection, Manual dipping (RTU gel)

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
• •	Indoor
Application method(s)	Method: Manual dipping Detailed description:
	Teat disinfectant, for direct application to lactating animals pre milking Applied directly to animal teats pre- milking via manual dipping application method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. Number and timing of application: 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)

4.1.1 Use-specific instructions for use

Applied directly to animal teats pre-milking via manual dipping application method. Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. 3 pre milking applications, per animal, per day. Apply a maximum of 10 ml product/ animal /application 4.1.2 Use-specific risk mitigation measures See section 5 - General Directions for Use 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment See section 5 - General Directions for Use 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging See section 5 - General Directions for Use 4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See section 5 - General Directions for Use 4.2 Use description

Use 2 - Use # 24 - Post-milking disinfection, Manual dipping (RTU gel)

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual dipping Detailed description:
	Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via manual dipping method.
Application rate(s) and frequencies	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before use. Number and timing of application:
	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)

4.2.1 Use-specific instructions for use

Applied directly to animal teats post milking via manual dipping method. Ready to use formulation containing 0.3% w/w lodine. Do not dilute before use. 2-3 post milking applications, per animal , per day. Apply a maximum of 10 ml product/ animal /application	
4.2.2 Use-specific risk mitigation measures	
See section 5 - General Directions for Use	
4.2.3 Where specific to the use, the particulars of likely direct or indirect effect instructions and emergency measures to protect the environment	ts, first aid
See section 5 - General Directions for Use	
4.2.4 Where specific to the use, the instructions for safe disposal of the produ	ıct and its
packaging	ict and its
See section 5 - General Directions for Use	
See section 5 - General Directions for Use	et unu its
See section 5 - General Directions for Use 4.2.5 Where specific to the use, the conditions of storage and shelf-life of the	
See section 5 - General Directions for Use 4.2.5 Where specific to the use, the conditions of storage and shelf-life of the under normal conditions of storage	
See section 5 - General Directions for Use 4.2.5 Where specific to the use, the conditions of storage and shelf-life of the under normal conditions of storage	

PT03 - Veterinary hygiene (Disinfectants) **Product type** Where relevant, an exact description of the authorised Scientific name: Bacteria Common name: other Target organism(s) (including development stage) Development stage: Scientific name: Yeast Common name: yeast Development stage: Indoor Field(s) of use Indoor Method: Semi-automatic dipping Application method(s) Detailed description: Teat disinfectant, for direct application to lactating animals post milking Applied directly to animal teats post milking via semi-automatic dipping method. Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Application rate(s) and Dilution (%): Ready to use formulation containing 0.3% w/w lodine. Do not dilute before frequencies Number and timing of application: 3 post milking applications, per animal per day. Apply a maximum of 10 ml product/ animal / application. Professional Category(ies) of users 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)

4.3.1 l	Jse-spe	ecific	instruc	tions	for	use
TIO: 1	JUC UN	-01110				450

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

4.3.2 Use-specific risk mitigation measures

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

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

See section 5 - General Directions for Use

4.4 Use description

Use 4 - Use # 26 - Pre and post-milking disinfection, manual dipping (RTU gel)

Product type

PT03 - Veterinary hygiene (Disinfectants)

Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: other Development stage:
	Scientific name: Yeast Common name: yeast Development stage:
Field(s) of use	Indoor
	Indoor
Application method(s)	Method: Manual dipping Detailed description:
	Teat disinfectant, for direct application to lactating animals pre and post milking Applied directly to animal teats pre and post milking via manual dipping application method.
Application rate(s) and	Application Rate: In use Iodine concentration of 3000mg/Kg (0.3% w/w) Dilution (%): Ready to use formulation containing 0.3% w/w Iodine. Do not dilute before
frequencies	use. Number and timing of application: 3 pre 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)

4.4.1 Use-specific instructions for use

Applied directly to animal teats pre and post milking via manual dipping application method. Ready to use formulation containing 0.3% w/w lodine. 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 10 ml product/ animal /application
1.4.2 Use-specific risk mitigation measures
Wear protective chemical resistant gloves when applying the product by dipping (glove material to be specified by the authorisation holder within the product information)
1.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid nstructions and emergency measures to protect the environment
See section 5 - General Directions for Use
1.4.4 Where specific to the use, the instructions for safe disposal of the product and its backaging
See section 5 - General Directions for Use.
.4.5 Where specific to the use, the conditions of storage and shelf-life of the product inder normal conditions of storage
See section 5 - General Directions for Use
5. General directions for use of the meta SPC
5.1. Instructions for use
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, 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)

5.2. Risk mitigation measures

This product can be used for pre- and post-milking disinfection in combination (up to 5 applications in total per animal per day). However, it should not be used in combination with a different iodine-based product.

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

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.

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.

5.4. Instructions for safe disposal of the product and its packaging

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

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 Do not store at temperatures above 30°C Shelf life 18 months

6. Other information

The hazard and precautionary statements shall be in Icelandic on the label.

The hazard statements in Icelandic:

H412 Skaðlegt lífi í vatni, hefur langvinn áhrif.

The precautionary statements in Icelandic:

P101 Ef leita þarf læknis skal hafa ílát eða merkimiða tiltæk.

P102 Geymist þar sem börn ná ekki til.

P273 Forðist losun út í umhverfi.

P501 Fargið innihaldi í samræmi við landsbundnar reglur.

P501 Fargið íláti í samræmi við landsbundnar reglur.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)

Deosan Activate Barrier AG216	Market area: EU
Agros Iodo Pós	Market area: EU
Povisyl espeso	Market area: EU
Povisyl espeso	Market area: EU

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

IS-0020496-0006 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
lodine		Active Substance	7553-56-2	231-442-4	0,3