

**COMMISSION IMPLEMENTING REGULATION (EU) 2019/403****of 13 March 2019****granting a Union authorisation for the biocidal product family 'Deosan Activate BPF based on Iodine'**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products <sup>(1)</sup>, and in particular Article 44(5) thereof,

Whereas:

- (1) On 7 July 2015, Diversey Europe Operations B.V. submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Deosan Activate BPF based on Iodine' ('the product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of United Kingdom agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-JN018376-30 in the Register for Biocidal Products.
- (2) The biocidal product family contains iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 <sup>(2)</sup>, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 20 December 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 6 July 2018, the Agency submitted to the Commission an opinion <sup>(3)</sup>, including the draft summary of the biocidal product characteristics ('SPC') of the product family and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (5) On 17 September 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

<sup>(1)</sup> OJ L 167, 27.6.2012, p. 1.

<sup>(2)</sup> Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

<sup>(3)</sup> ECHA opinion of 6 July 2018 on the Union authorisation of 'Deosan Activate BPF based on Iodine' (ECHA/BPC/207/2018).

HAS ADOPTED THIS REGULATION:

*Article 1*

A Union authorisation is granted to Diversey Europe Operations B.V. for the biocidal product family 'Deosan Activate BPF based on Iodine' with authorisation number EU-0019228-0000.

The Union authorisation is valid from 3 April 2019 until 31 March 2029.

The Union authorisation is subject to compliance with the summary of the biocidal product characteristics set out in the Annex.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 March 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

**Summary of product characteristics for a biocidal product family**

Deosan Activate BPF based on Iodine

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019228-0000

R4BP asset number: EU-0019228-0000

## PART I

**FIRST INFORMATION LEVEL****1. ADMINISTRATIVE INFORMATION****1.1. Family name**

|      |                                     |
|------|-------------------------------------|
| Name | Deosan Activate BPF based on Iodine |
|------|-------------------------------------|

**1.2. Product type(s)**

|                 |                                           |
|-----------------|-------------------------------------------|
| 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         | Maarssenbroeksedijk 2, 3542DN Utrecht, Netherlands |
| Authorisation number                         | EU-0019228-0000 |                                                    |
| R4BP asset number                            | EU-0019228-0000 |                                                    |
| Date of the authorisation                    | 3 April 2019    |                                                    |
| Expiry date of the authorisation             | 31 March 2029   |                                                    |

**1.4. Manufacturer(s) of the biocidal products**

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

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

|                                 |                                           |
|---------------------------------|-------------------------------------------|
| Active substance                | Iodine                                    |
| Name of manufacturer            | ACF Minera S.A.                           |
| Address of manufacturer         | San Martin No 499, 1100000 Iquique Chile  |
| Location of manufacturing sites | Lagunas mine, 118 0000 Pozo Almonte Chile |

|                                 |                                                                |
|---------------------------------|----------------------------------------------------------------|
| Active substance                | Iodine                                                         |
| Name of manufacturer            | Sociedad Quimica y Minera (SQM) S.A.                           |
| Address of manufacturer         | Los Militares 4290, Piso 4, Las Condes, 8320000 Santiago Chile |
| Location of manufacturing sites | Nueva Victoria plant, 5090000 Pedro de Valdivia plant Chile    |

|                                 |                                                        |
|---------------------------------|--------------------------------------------------------|
| Active substance                | Iodine                                                 |
| Name of manufacturer            | Cosayach Nitratos S.A.                                 |
| Address of manufacturer         | Hnos Amunátegui 178, 8320000 Santiago Chile            |
| Location of manufacturing sites | S.C.M. Cosayach Cala Cala, 118 0000 Pozo Almonte Chile |

|                                 |                                                                                  |
|---------------------------------|----------------------------------------------------------------------------------|
| Active substance                | Iodine                                                                           |
| Name of manufacturer            | Nihon Tennen Gas Development Co., Ltd                                            |
| Address of 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                | Iodine                                                                      |
| Name of manufacturer            | ISE Chemicals Corporation                                                   |
| Address of manufacturer         | 3-1, Kyobashi 1-Chome, 104-0031 Tokyo Japan                                 |
| Location of manufacturing sites | Shirasto Plant (3695 Kitaimaizumi, Oamishirasato City, 299-3201 Chiba Japan |

|                                 |                                                                         |
|---------------------------------|-------------------------------------------------------------------------|
| Active substance                | Iodine                                                                  |
| Name of manufacturer            | Atacama Minerals SCM                                                    |
| Address of manufacturer         | Coronel Pereira No 72 Of. 701, Las Condes, 8320000 Santiago Chile       |
| Location of manufacturing sites | Atacama Minerals SCM, Aguas Blancas Facility, 3580000 Antofagasta Chile |

## 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 (%) |     |
|-------------|------------|------------------|------------|-----------|-------------|-----|
|             |            |                  |            |           | Min         | Max |
| Iodine      |            | Active Substance | 7553-56-2  | 231-442-4 | 0,3         | 1,6 |

## 2.2. Type(s) of formulation

|                |                                                                             |
|----------------|-----------------------------------------------------------------------------|
| Formulation(s) | AL — Any other liquid<br>SL — Soluble concentrate<br>GW — Water soluble gel |
|----------------|-----------------------------------------------------------------------------|

## PART II

## SECOND INFORMATION LEVEL — META SPC(S)

## META SPC 1

## 1. META SPC 1 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 1 identifier

|            |                                                |
|------------|------------------------------------------------|
| Identifier | Meta SPC 1 — Deosan Activate BPF — Concentrate |
|------------|------------------------------------------------|

## 1.2. Suffix to the authorisation number

|        |     |
|--------|-----|
| Number | 1-1 |
|--------|-----|

## 1.3. Product type(s)

|                 |                                           |
|-----------------|-------------------------------------------|
| Product type(s) | PT03 — Veterinary hygiene (Disinfectants) |
|-----------------|-------------------------------------------|

## 2. META SPC 1 COMPOSITION

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 1

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

## 2.2. Type(s) of formulation of the meta SPC 1

|                |                          |
|----------------|--------------------------|
| Formulation(s) | SL — Soluble concentrate |
|----------------|--------------------------|

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

|                          |                                                                                                                                                                                                                                                                                     |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard statements        | Harmful to aquatic life with long lasting effects.                                                                                                                                                                                                                                  |
| Precautionary statements | If medical advice is needed, have product container or label at hand.<br>Keep out of reach of children.<br>Avoid release to the environment.<br>Dispose of contents to in accordance with national regulations.<br>Dispose of container to in accordance with national regulations. |

## 4. AUTHORISED USE(S) OF THE META SPC 1

## 4.1. Use description

**Table 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                  |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                             |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre milking.<br>Applied directly to animal teats pre milking via manual dipping method                                                                                                                                                                                                            |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre milking applications, per animal, per day<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                       |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 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

Table 2. Use # 2 – Pre-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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                    |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre milking via manual foaming method                                                                                                                                                                                                    |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre milking applications, per animal, per day<br>Apply a maximum of 5 ml/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                              |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 mitigation measures

See section 5 — General Directions for Use

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

See section 5 — General Directions for Use

## 4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5 — General Directions for Use

## 4.2.5. 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

## 4.3. Use description

**Table 3. Use # 3 – Pre-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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                 |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                            |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre milking via manual spraying method.                                                                                                                                                                                                         |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre milking applications, per animal, per day<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                      |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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

**Table 4. Use # 4 – 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                   |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                              |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual dipping method.                                                                                                                                                                                                           |
| Application rate(s) and frequency                          | In use Iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 post milking applications, per animal, per day<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                        |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)                                                                                                                                                                                                                                            |

## 4.4.1. Use-specific instructions 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 mitigation measures

See section 5 — General Directions for Use

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

See section 5 — General Directions for Use

## 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

**Table 5. Use # 5 – 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                  |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                             |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual foaming method.                                                                                                                                                                                                          |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 post milking applications, per animal, per day<br>Apply a maximum of 5 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                       |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>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

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

See section 5 — General Directions for Use

## 4.5.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

See section 5 — General Directions for Use

## 4.5.5. 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

## 4.6. Use description

**Table 6. Use # 6 – 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                   |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                              |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual spraying method.                                                                                                                                                                                                         |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 post milking applications, per animal, per day<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                        |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>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 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 packaging

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

**Table 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Application method(s)                                      | Automatic spraying<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via automatic spraying method.                                                                                                                                                                                                                                                      |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>5 post milking applications, per animal, per day. Not to be combined with pre-milking disinfection.<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE Intermediate Bulk Container (IBC)                                                                                                                                                                                                                                                                                               |

## 4.7.1. Use-specific instructions 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, 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

**Table 8. Use # 8 – Post-milking disinfection, 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                   |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                              |
| Application method(s)                                      | Semi-automatic dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via semi-automatic dipping method.                                                                                                                                                                                           |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 post-milking applications, per animal, per day<br>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<br>200 litre HDPE or f-HDPE drum<br>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.

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 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

**Table 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                                                             |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual dipping method                                                                                                                                                                                                                                      |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total)<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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

## 4.9.5. 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

**Table 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                                                    |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                                                               |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual foaming method                                                                                                                                                                                                                             |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total)<br>Apply a maximum of 5 ml/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                                                         |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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

## 4.10.5. 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

**Table 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)           | Bacteria<br>Yeast                                                                                                                                                                                                                                                                                                                                                                                                             |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual spraying method.                                                                                                                                                                                                                                   |
| Application rate(s) and frequency                          | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>For products containing 1,5 % iodine: Dilute 1 part of product to 4 parts water to achieve 0,3 % in use iodine concentration.<br>For products with another concentration this instruction should be adapted.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total)<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users                                     | Professional                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Pack sizes and packaging material                          | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)                                                                                                                                                                                                                                                                                      |

## 4.11.1. 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 spraying application method.

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

4.11.5. *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 <sup>(1)</sup> OF THE META SPC 1

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 3 000 mg/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 3 000 mg/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.

<sup>(1)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

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**

None

#### 7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1**

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

|                      |                                                  |                  |            |           |             |
|----------------------|--------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate Pre AG106<br>Deosan Activate Pre |                  |            |           |             |
| Authorisation number | EU-0019228-0001 1-1                              |                  |            |           |             |
| Common name          | IUPAC name                                       | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                  | Active Substance | 7553-56-2  | 231-442-4 | 1,5         |

##### 7.2. **Trade name(s), authorisation number and specific composition of each individual product**

|                      |                                                                                                                                                                                                               |                  |            |           |             |
|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate Pre/Post Conc. AG218<br>Deosan Activate Pre/Post Conc.<br>Deosan Hitech concentrate<br>Deosan Activate Pre/Post Plus Conc. AG218<br>Deosan Activate Pre/Post Plus Conc.<br>Iodine Concentrate |                  |            |           |             |
| Authorisation number | EU-0019228-0002 1-1                                                                                                                                                                                           |                  |            |           |             |
| Common name          | IUPAC name                                                                                                                                                                                                    | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                                                                                                                                                                               | Active Substance | 7553-56-2  | 231-442-4 | 1,5         |

**META SPC 2**

## 1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

|            |                                               |
|------------|-----------------------------------------------|
| Identifier | Meta SPC 2 — Deosan Activate BPF – RTU liquid |
|------------|-----------------------------------------------|

1.2. **Suffix to the authorisation number**

|        |     |
|--------|-----|
| Number | 1-2 |
|--------|-----|

1.3. **Product type(s)**

|                 |                                           |
|-----------------|-------------------------------------------|
| Product type(s) | PT03 — Veterinary hygiene (Disinfectants) |
|-----------------|-------------------------------------------|

## 2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

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

2.2. **Type(s) of formulation of the meta SPC 2**

|                |                       |
|----------------|-----------------------|
| Formulation(s) | AL — Any other liquid |
|----------------|-----------------------|

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

|                          |                                                                                                                                                                                                                                                                                     |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard statements        | Harmful to aquatic life with long lasting effects.                                                                                                                                                                                                                                  |
| Precautionary statements | If medical advice is needed, have product container or label at hand.<br>Keep out of reach of children.<br>Avoid release to the environment.<br>Dispose of contents to in accordance with national regulations.<br>Dispose of container to in accordance with national regulations. |

## 4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description****Table 12. Use # 1 – Pre-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)           | Bacteria<br>Yeast                                                                                                                                                       |
| Field(s) of use                                            | Indoor                                                                                                                                                                  |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre-milking via manual dipping methods |

|                                   |                                                                                                                                                                                                                                                        |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre-milking applications, per animal, per day.<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                           |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 iodine. 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**

**Table 13. Use # 2 – 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)           | Bacteria<br>Yeast                                                                                                                                                       |
| Field(s) of use                                            | Indoor                                                                                                                                                                  |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre-milking via manual foaming method. |

|                                   |                                                                                                                                                                                                                                                       |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use Iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w Iodine. Do not dilute before use.<br>3 pre milking applications, per animal, per day.<br>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<br>200 litre HDPE or f-HDPE drum<br>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 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

#### 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 effects, first aid instructions and emergency measures to protect the environment*

See section 5 — General Directions for Use

#### 4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5 — General Directions for Use

#### 4.2.5. *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

### 4.3. **Use description**

**Table 14. Use # 3 – 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)           | Bacteria<br>Yeast                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                    |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre-milking via manual spraying method. |

|                                   |                                                                                                                                                                                                                                                        |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w Iodine. Do not dilute before use.<br>3 pre milking applications, per animal, per day.<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                           |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE Intermediate Bulk Container (IBC)                                                                                                               |

#### 4.3.1. *Use-specific instructions for use*

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

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

#### 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**

**Table 15. Use # 4 – 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)           | Bacteria<br>Yeast                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                    |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual dipping method. |

|                                   |                                                                                                                                                                                                                                                         |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications, per animal, per day.<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                            |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE Intermediate Bulk Container (IBC)                                                                                                                |

#### 4.4.1. *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 iodine. Do not dilute before use.

3 post milking applications, per animal, per day.

Apply a maximum of 10 ml product/animal/application

#### 4.4.2. *Use-specific risk mitigation measures*

See section 5 — General Directions for Use

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

See section 5 — General Directions for Use

#### 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**

**Table 16. Use # 5 – 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)           | Bacteria<br>Yeast                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                    |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual foaming method. |

|                                   |                                                                                                                                                                                                                                                        |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications, per animal, per day.<br>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<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE Intermediate Bulk Container (IBC)                                                                                                                 |

#### 4.5.1. *Use-specific instructions for use*

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

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

#### 4.5.2. *Use-specific risk mitigation measures*

See section 5 — General Directions for Use

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

See section 5 — General Directions for Use

#### 4.5.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5 — General Directions for Use

#### 4.5.5. *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

### 4.6. **Use description**

**Table 17. Use # 6 – Post-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)           | Bacteria<br>Yeast                                                                                                                                                           |
| Field(s) of use                                            | Indoor                                                                                                                                                                      |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual spraying method. |

|                                   |                                                                                                                                                                                                                                                         |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications, per animal, per day.<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                            |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 iodine. 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)

4.6.3. *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

4.6.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5 — General Directions for Use

4.6.5. *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**

**Table 18. Use # 7 – Post-milking disinfection, automatic spraying (not to be combined with a pre-milking disinfection (RTU liquid))**

|                                                            |                                                                                                                                                                                   |
|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product type                                               | PT03 — Veterinary hygiene (Disinfectants)                                                                                                                                         |
| Where relevant, an exact description of the authorised use | —                                                                                                                                                                                 |
| Target organism(s) (including development stage)           | Bacteria<br>Yeast                                                                                                                                                                 |
| Field(s) of use                                            | Indoor                                                                                                                                                                            |
| Application method(s)                                      | Automatic spraying<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via automatic spraying method. |

|                                   |                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>5 post milking applications, per animal, per day. Not to be combined with iodine based pre-milking disinfection.<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                                                                                           |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>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 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

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**

**Table 19. Use # 8 – Post-milking disinfection, semi-automatic dipping (RTU liquid)**

|                                                            |                                                                                                                                                                                           |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product type                                               | PT03 — Veterinary hygiene (Disinfectants)                                                                                                                                                 |
| Where relevant, an exact description of the authorised use | —                                                                                                                                                                                         |
| Target organism(s) (including development stage)           | Bacteria<br>Yeast                                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                                    |
| Application method(s)                                      | Semi-automatic dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via semi-automatic dipping method. |

|                                   |                                                                                                                                                                                                                                                        |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications per animal, per day.<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                           |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 iodine. 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**

**Table 20. Use # 9 – Pre and 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)           | Bacteria<br>Yeast                                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                                    |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual dipping methods |

|                                   |                                                                                                                                                                                                                                                                                                   |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total).<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                                                                      |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)                                                                                                                                                          |

4.9.1. *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 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 10 ml product/animal/application

4.9.2. *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)

4.9.3. *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

4.9.5. *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**

**Table 21. Use # 10 – Pre and 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)           | Bacteria<br>Yeast                                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                                    |
| Application method(s)                                      | Manual foaming<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual foaming method. |

|                                   |                                                                                                                                                                                                                                                                                                  |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total).<br>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<br>200 litre HDPE or f-HDPE drum<br>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 iodine. 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

#### 4.10.2. *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)

#### 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

#### 4.10.5. *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**

**Table 22. Use # 11 – Pre and post 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)           | Bacteria<br>Yeast                                                                                                                                                                           |
| Field(s) of use                                            | Indoor                                                                                                                                                                                      |
| Application method(s)                                      | Manual spraying<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual spraying method. |

|                                   |                                                                                                                                                                                                                                                                                                   |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total).<br>Apply a maximum of 15 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                                                                      |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>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 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

#### 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

#### 4.11.5. *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 <sup>(2)</sup> OF THE META SPC 2

#### 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 3 000 mg/Kg (0,3 % w/w)

<sup>(2)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

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 3 000 mg/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**

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 30 °C

Shelf life 24 months

6. **OTHER INFORMATION**

None

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**

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

|                      |                                                          |                  |            |           |             |
|----------------------|----------------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate Pre RTU AG108<br>Deosan Activate Pre RTU |                  |            |           |             |
| Authorisation number | EU-0019228-0003 1-2                                      |                  |            |           |             |
| Common name          | IUPAC name                                               | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                          | Active Substance | 7553-56-2  | 231-442-4 | 0,3         |

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

|                      |                                                                                                                                                                      |                  |            |           |             |
|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate Pre/Post AG217<br>Deosan Activate Pre/Post<br>Iodine Plus Pre & Post<br>Deosan D4T Super AG211<br>Agros Iodo<br>Agros Iodo Multi<br>Poviclyn liquido |                  |            |           |             |
| Authorisation number | EU-0019228-0004 1-2                                                                                                                                                  |                  |            |           |             |
| Common name          | IUPAC name                                                                                                                                                           | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                                                                                                                                      | Active Substance | 7553-56-2  | 231-442-4 | 0,3         |

7.3. **Trade name(s), authorisation number and specific composition of each individual product**

|                      |                                                                                                                                                |                  |            |           |             |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate PVP Plus AG215<br>Deosan Activate PVP Plus<br>Agros Iodo-Prev POS-Ordenha<br>Deosan Hitech 2 AG214<br>Iodine Teat Dip Solution |                  |            |           |             |
| Authorisation number | EU-0019228-0005 1-2                                                                                                                            |                  |            |           |             |
| Common name          | IUPAC name                                                                                                                                     | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                                                                                                                | Active Substance | 7553-56-2  | 231-442-4 | 0,3         |

**META SPC 3**

## 1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

|            |                                            |
|------------|--------------------------------------------|
| Identifier | Meta SPC 3 — Deosan Activate BPF – RTU gel |
|------------|--------------------------------------------|

1.2. **Suffix to the authorisation number**

|        |     |
|--------|-----|
| Number | 1-3 |
|--------|-----|

1.3. **Product type(s)**

|                 |                                           |
|-----------------|-------------------------------------------|
| Product type(s) | PT03 — Veterinary hygiene (Disinfectants) |
|-----------------|-------------------------------------------|

## 2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

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

2.2. **Type(s) of formulation of the meta SPC 3**

|                |                        |
|----------------|------------------------|
| Formulation(s) | GW — Water soluble gel |
|----------------|------------------------|

## 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

|                          |                                                                                                                                                                                                                                                                                     |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard statements        | Harmful to aquatic life with long lasting effects.                                                                                                                                                                                                                                  |
| Precautionary statements | If medical advice is needed, have product container or label at hand.<br>Keep out of reach of children.<br>Avoid release to the environment.<br>Dispose of contents to in accordance with national regulations.<br>Dispose of container to in accordance with national regulations. |

## 4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description****Table 23. Use # 1 – 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)           | Bacteria<br>Yeast                                                                                                                                                                    |
| Field(s) of use                                            | Indoor                                                                                                                                                                               |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre milking<br>Applied directly to animal teats pre- milking via manual dipping application method. |

|                                   |                                                                                                                                                                                                                                                        |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre milking applications, per animal, per day.<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                           |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 iodine. 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**

**Table 24. Use # 2 – 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)           | Bacteria<br>Yeast                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                    |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via manual dipping method. |

|                                   |                                                                                                                                                                                                                                                         |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications, per animal, per day.<br>apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                            |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 iodine. 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 effects, first aid instructions and emergency measures to protect the environment*

See section 5 — General Directions for Use

#### 4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See section 5 — General Directions for Use

#### 4.2.5. *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

### 4.3. **Use description**

**Table 25. Use # 3 – Post-milking disinfection, semi-automatic dipping (RTU gel)**

|                                                            |                                                                                                                                                                                           |
|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product type                                               | PT03 — Veterinary hygiene (Disinfectants)                                                                                                                                                 |
| Where relevant, an exact description of the authorised use | —                                                                                                                                                                                         |
| Target organism(s) (including development stage)           | Bacteria<br>Yeast                                                                                                                                                                         |
| Field(s) of use                                            | Indoor                                                                                                                                                                                    |
| Application method(s)                                      | Semi-automatic dipping<br>Teat disinfectant, for direct application to lactating animals post milking<br>Applied directly to animal teats post milking via semi-automatic dipping method. |

|                                   |                                                                                                                                                                                                                                                         |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 post milking applications, per animal per day.<br>Apply a maximum of 10 ml product/animal/application. |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                            |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HPDE Intermediate Bulk Container (IBC)                                                                                                                |

#### 4.3.1. 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 iodine. 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

**Table 26. Use # 4 – 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)           | Bacteria<br>Yeast                                                                                                                                                                                     |
| Field(s) of use                                            | Indoor                                                                                                                                                                                                |
| Application method(s)                                      | Manual dipping<br>Teat disinfectant, for direct application to lactating animals pre and post milking<br>Applied directly to animal teats pre and post milking via manual dipping application method. |

|                                   |                                                                                                                                                                                                                                                                                                  |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Application rate(s) and frequency | In use iodine concentration of 3 000 mg/Kg (0,3 % w/w) –<br>Ready to use formulation containing 0,3 % w/w iodine. Do not dilute before use.<br>3 pre and 3 post milking applications, per animal, per day (up to 5 applications in total)<br>Apply a maximum of 10 ml product/animal/application |
| Category(ies) of users            | Professional                                                                                                                                                                                                                                                                                     |
| Pack sizes and packaging material | 1, 5 and 20 litre HDPE or f-HDPE canister<br>200 litre HDPE or f-HDPE drum<br>950 litre HDPE or f-HDPE 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 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 10 ml product/animal/application

#### 4.4.2. *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)

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

See section 5 — General Directions for Use

#### 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

### 5. GENERAL DIRECTIONS FOR USE <sup>(3)</sup> OF THE META SPC 3

#### 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 3 000 mg/Kg (0,3 % w/w)

<sup>(3)</sup> Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

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 3 000 mg/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

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 30 °C

Shelf life 18 months

**6. OTHER INFORMATION**

None

**7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3****7.1. Trade name(s), authorisation number and specific composition of each individual product**

|                      |                                                                   |                  |            |           |             |
|----------------------|-------------------------------------------------------------------|------------------|------------|-----------|-------------|
| Trade name(s)        | Deosan Activate Barrier AG216<br>Agros Iodo Pós<br>Povisyl espeso |                  |            |           |             |
| Authorisation number | EU-0019228-0006 1-3                                               |                  |            |           |             |
| Common name          | IUPAC name                                                        | Function         | CAS number | EC number | Content (%) |
| Iodine               |                                                                   | Active Substance | 7553-56-2  | 231-442-4 | 0,3         |