

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab Iodine PT3 Family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018398-0000

R4BP asset number: EU-0018398-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

| | |
|------|--------------------------|
| Name | Ecolab Iodine PT3 Family |
| | |

1.2. Product type(s)

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

1.3. Authorisation holder

| | | |
|--|-------------------|--|
| Name and address of the authorisation holder | Name | Ecolab Deutschland GmbH |
| | Address | Ecolab-Allee 1, 40789 Monheim, Germany |
| Authorisation number | EU-0018398-0000 | |
| <i>R4BP asset number</i> | EU-0018398-0000 | |
| Date of the authorisation | 11 October 2018 | |
| Expiry date of the authorisation | 30 September 2028 | |

1.4. Manufacturer(s) of the biocidal products

| | |
|---------------------------------|---|
| Name of manufacturer | Ecolab Europe GmbH |
| Address of manufacturer | Richtistrasse 7, 8304 Wallisellen Switzerland |
| Location of manufacturing sites | Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL |

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

WAY, BAGLAN ENERGY PARK, NEATH,
SA11 2GA South Wales United Kingdom
Ecolab Leeds, LOTHERTON WAY,
GARFORTH, LEEDS LS25 2JY Leeds
United Kingdom
Ecolab Rovigo, Viale del Lavoro 10, 45100
Rovigo Italy
Ecolab Biebesheim Nalco Deutschland
Manufacturing GmbH und Co.KG, Justus-
von-Liebig-Str. 11 D-64584 Biebesheim
Germany
Ecolab NETHERLANDS BV,
NL01ECOLAB, BRUGWAL 11 3432NZ
NIEUWEGEIN Netherlands
Ecolab Weavergate, ECOLAB
WEAVERGATE PLANT WINNINGTON
AVENUE, NORTHWICH CHESHIRE CW8
3AA NORTHWICH United Kingdom
Ecolab Mullingar, Forest Park, Mullingar
Ind. Estate, Mullingar, Co. Zone C
Westmeath Ireland
Ecolab Maribor, Ecolab d.o.o., Vajngerlova 4
2000 Maribor Slovenia
Ecolab Rozzano, VIA GRANDI 9/11 20089
ROZZANO Italy
Ecolab B.V.B.A, Havenlaan: 4 3980
Tessengerlo Belgium
Ecolab CELRA, Nalco Española
Manufacturing, SLU C/Tramuntana s/n,
Polígono Industrial de Celrà 17460 CELRÀ
Spain
Ecolab Chalons Ecolab production France
SAS, BP509 Avenue de Général Patton
51006 Châlons-en-Champagne France
Ecolab Mandra, 25km Old National Road
Athens Mandra, oo Attica Greece
NALCO FINLAND MANUFACTURING
OY, Kivikumuntie 1 FIN-07955 Tesjoki
Finland

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

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | |
|---------------------------------|--|
| Active substance | Iodine |
| Name of manufacturer | ACF Minera S.A. |
| Address of manufacturer | San Martín No 499 00 Iquique Chile |
| Location of manufacturing sites | Lagunas mine 00 Pozo Almonte Chile |
| Active substance | Iodine |
| Name of manufacturer | SQM S.A. |
| Address of manufacturer | Los Militares 4290 Piso 4 Santiago Chile |
| Location of manufacturing sites | Nueva Victoria plant 00 Pedro de Valdivia Chile |
| Active substance | Iodine |
| Name of manufacturer | Cosayach Nitratos S.A. |
| Address of manufacturer | Amunategui 178 00 Santiago Chile |
| Location of manufacturing sites | S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile |
| Active substance | Iodine |
| Name of manufacturer | Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd |
| Address of manufacturer | 661 Mobara Chiba 297-8550 Mobara City Japan |
| Location of manufacturing sites | Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 Chiba Japan |

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 |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 | 3 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 | 0,33 |

2.2. Type(s) of formulation

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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 |
|------------|------------|

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 |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 | 0,11 |

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

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
|-------------|-----------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

| | |
|--------------------------|--|
| Hazard statements | |
| Precautionary statements | |

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

4.1. Use description

TABLE 1. USE # 1 – TEAT DIPS FOR POST-MILKING DISINFECTION

| | |
|--|--|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Manual dipping using a dip cup - 3-10 ml (dipping) 1-3 post-milking disinfections per day |
| Application rate(s) and frequency | 3-10 ml (dipping) Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | container, Plastic: HDPE, 0,5-1 000 l |

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 1

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

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 general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

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

See general directions for use of meta SPC 1

5. GENERAL DIRECTIONS FOR USE⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

Product to be applied post-milking by use of a dipping cup.

The products must be brought to temperatures above 20 °C before use.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

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) | Ioklar Super Dip D | | | | |
|-----------------------------|---------------------|------------------|------------|-----------|-------------|
| Authorisation number | EU-0018398-0001 1-1 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 |

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

| Trade name(s) | IoKlar Superdip | | | | |
|-----------------------------|---------------------|------------------|------------|-----------|-------------|
| Authorisation number | EU-0018398-0002 1-1 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 |

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

| | |
|------------|------------|
| Identifier | meta SPC 2 |
|------------|------------|

*Changes to legislation: There are currently no known outstanding effects for the Commission
Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)*

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 |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1,35 | 1,35 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,15 | 0,15 |

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

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
|-------------|-----------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

| | |
|--------------------------|--|
| Hazard statements | |
| Precautionary statements | |

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

4.1. Use description

TABLE 2. USE # 1 – TEAT DIPS FOR POST-MILKING DISINFECTION

| | |
|--|---|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |

| | |
|-----------------------------------|---|
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Manual dipping using a dip cup |
| Application rate(s) and frequency | Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 2

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 2

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 general directions for use of meta SPC 2

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

See general directions for use of meta SPC 2

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

See general directions for use of meta SPC 2

5. GENERAL DIRECTIONS FOR USE⁽²⁾ OF THE META SPC 2

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

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

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

| | | | | | |
|-----------------------------|--|------------------|-------------------|------------------|--------------------|
| Trade name(s) | Io-Shield D IoShield MEPA Barrier D BARIOPROTECT MS Cow Udder BLOCK Iodocop EXTRA | | | | |
| Authorisation number | EU-0018398-0003 1-2 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1,35 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,15 |

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

| | | | | | |
|-----------------------------|---|------------------|-------------------|------------------|--------------------|
| Trade name(s) | IoDark Iodocop EXTRA GREEN Mammizan Protect MS Cow Udder BLACK | | | | |
| Authorisation number | EU-0018398-0004 1-2 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1,35 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,15 |

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

| | |
|------------|------------|
| Identifier | meta SPC 3 |
|------------|------------|

1.2. Suffix to the authorisation number

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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 |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 2,45 | 2,45 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,27 | 0,27 |

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

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
| | |

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

| | |
|--------------------------|--|
| Hazard statements | Harmful to aquatic life with long lasting effects. |
| Precautionary statements | Avoid release to the environment. |

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

4.1. Use description

TABLE 3. USE # 1 – TEAT DIPS OR SPRAYS FOR POST-MILKING DISINFECTION

| | |
|--|--|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |

| | |
|-----------------------------------|--|
| Application method(s) | Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot. |
| Application rate(s) and frequency | Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |

4.1.1. *Use-specific instructions for use*

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking, using manual or automatic equipment. Post-milking: Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

See also general instructions for use of meta SPC 3.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

See also general risk mitigation measures of meta SPC 3.

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

4.2. **Use description**

TABLE 4. USE # 2 – TEAT DIPS OR SPRAYS FOR PRE-MILKING DISINFECTION

| | |
|--|---|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts |

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | |
|-----------------------------------|---|
| Field(s) of use | Indoor Pre-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer. |
| Application rate(s) and frequency | Pre-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |

4.2.1. *Use-specific instructions for use*

Product to be applied by dipping or spraying on teats of milk-producing animals pre-milking, using manual equipment.

Pre-milking: Clean teats by wiping with cloth before disinfection. Apply product on the whole teats and leave it for 1 min. Then wipe with a single use paper or a towel.

See also general instructions for use of meta SPC3.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

See also general risk mitigation measures of meta SPC3.

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 general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

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

See general directions for use of meta SPC 3

5. GENERAL DIRECTIONS FOR USE⁽³⁾ OF THE META SPC 3

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

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

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

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) | IoKlar Multi MEPA Iospray Plus D ASTRI-IO DESINTEC MH-Iodine S | | | | |
| Authorisation number | EU-0018398-0005 1-3 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 2,45 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,27 |

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

| | |
|------------|------------|
| Identifier | meta SPC 4 |
|------------|------------|

1.2. **Suffix to the authorisation number**

| | |
|--------|-----|
| Number | 1-4 |
|--------|-----|

1.3. **Product type(s)**

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

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

| | | | | | |
|--------------------|-------------------|-----------------|-------------------|------------------|--------------------|
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|--------------------|-------------------|-----------------|-------------------|------------------|--------------------|

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | | | | | Min | Max |
|-----------------------------|------------------|------------|-----------|--|------------|------------|
| Polyvinylpyrrolidone iodine | Active substance | 25655-41-8 | | | 1 | 1 |
| Iodine | Active substance | 7553-56-2 | 231-442-4 | | 0,11 | 0,11 |

2.2. Type(s) of formulation of the meta SPC 4

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
|-------------|-----------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

| | |
|--------------------------|--|
| Hazard statements | |
| Precautionary statements | |

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

4.1. Use description

TABLE 5. USE # 1 – TEAT DIPS OR SPRAYS FOR POST-MILKING DISINFECTION

| | |
|--|---|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot. |
| Application rate(s) and frequency | Post-milking application 1x - 3x per day. Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats). |
| Category(ies) of users | Professional |

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | |
|-----------------------------------|--------------------------------|
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |
|-----------------------------------|--------------------------------|

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 4

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

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

See general directions for use of meta SPC 4

5. GENERAL DIRECTIONS FOR USE⁽⁴⁾ OF THE META SPC 4

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

5.2. **Risk mitigation measures**

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

| | |
|---------------|--|
| Trade name(s) | Veloucid Spray D VelouCid Spray MEPA Soft Spray D ASTRI-UC SAC WINTERSPRAY |
|---------------|--|

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | | | | | |
|-----------------------------|---------------------|------------------|-------------------|------------------|--------------------|
| Authorisation number | EU-0018398-0006 1-4 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 |

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

| | |
|------------|------------|
| Identifier | meta SPC 5 |
|------------|------------|

1.2. Suffix to the authorisation number

| | |
|--------|-----|
| Number | 1-5 |
|--------|-----|

1.3. Product type(s)

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

2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|-----------------------------|------------|------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 | 0,11 |

2.2. Type(s) of formulation of the meta SPC 5

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
|-------------|-----------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

| | |
|--------------------------|--|
| Hazard statements | |
| Precautionary statements | |

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. Use description

TABLE 6. USE # 1 – TEAT DIPS FOR POST-MILKING DISINFECTION

| | |
|--|--|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Dipping Manual dipping using a dip cup. |
| Application rate(s) and frequency | Post-milking application 1x – 3x per day Per milking event 3-10 ml of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 5

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

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

See general directions for use of meta SPC 5

*Changes to legislation: There are currently no known outstanding effects for the Commission
Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)*

5. GENERAL DIRECTIONS FOR USE⁽⁵⁾ OF THE META SPC 5

5.1. Instructions for use

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 18 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

| Trade name(s) | Veloucid D VelouCid MEPA Care D Cremadip MS Cow Udder SEPIA | | | | |
|-----------------------------|---|------------------|------------|-----------|-------------|
| Authorisation number | EU-0018398-0007 1-5 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,11 |

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

| | |
|------------|------------|
| Identifier | meta SPC 6 |
|------------|------------|

1.2. Suffix to the authorisation number

| | |
|--------|-----|
| Number | 1-6 |
|--------|-----|

1.3. Product type(s)

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

2. META SPC 6 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) | |
|-----------------------------|------------|------------------|------------|-----------|-------------|------|
| | | | | | Min | Max |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1,35 | 1,35 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,15 | 0,15 |

2.2. Type(s) of formulation of the meta SPC 6

| | |
|-------------|-----------------------|
| Formulation | AL — Any other liquid |
|-------------|-----------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

| | |
|--------------------------|--|
| Hazard statements | |
| Precautionary statements | |

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. Use description

TABLE 7. USE # 1 – TEAT DIPS OR SPRAYS FOR POST-MILKING DISINFECTION

| | |
|--|---|
| Product Type | PT03 — Veterinary hygiene (Disinfectants) |
| Where relevant, an exact description of the authorised use | — |
| Target organism(s) (including development stage) | Bacteria Yeasts Enveloped viruses |
| Field(s) of use | Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep) |
| Application method(s) | Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or |

| | |
|-----------------------------------|---|
| | Manual spraying using an electronic sprayer or Automated spraying by robot. |
| Application rate(s) and frequency | Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats). |
| Category(ies) of users | Professional |
| Pack sizes and packaging material | 0,5 l – 1 000 l HDPE container |

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 6

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 6

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

See general directions for use of meta SPC 6

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

See general directions for use of meta SPC 6

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

See general directions for use of meta SPC 6

5. GENERAL DIRECTIONS FOR USE⁽⁶⁾ OF THE META SPC 6

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

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

5.2. **Risk mitigation measures**

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

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

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

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

| | | | | | |
|-----------------------------|---|------------------|-------------------|------------------|--------------------|
| Trade name(s) | MEPA Barrier Spray D IoShield Spray QUARESS-Barrier | | | | |
| Authorisation number | EU-0018398-0008 1-6 | | | | |
| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
| Polyvinylpyrrolidone iodine | | Active substance | 25655-41-8 | | 1,35 |
| Iodine | | Active substance | 7553-56-2 | 231-442-4 | 0,15 |

Changes to legislation: There are currently no known outstanding effects for the Commission
Implementing Regulation (EU) 2018/1258, ANNEX. (See end of Document for details)

- (1) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.
- (2) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.
- (3) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.
- (4) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.
- (5) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.
- (6) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC6.

Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258, ANNEX.