

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	
R4BP asset number	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	Richtstrasse 7, 8304 Wallisellen Switzerland
Location of manufacturing sites	Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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
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1.2. Suffix to the authorisation number

Number	1-1
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1.3. Product type(s)

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

Status: Point in time view as at 31/12/2020.

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

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.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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
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Status: Point in time view as at 31/12/2020.

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

1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

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

Status: Point in time view as at 31/12/2020.

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

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.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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

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Status: Point in time view as at 31/12/2020.

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

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)	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
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1.2. Suffix to the authorisation number

Status: Point in time view as at 31/12/2020.

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

Number	1-3
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1.3. Product type(s)

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

Status: Point in time view as at 31/12/2020.

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

	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	—

Status: Point in time view as at 31/12/2020.

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

Target organism(s) (including development stage)	Bacteria Yeasts
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.

Status: Point in time view as at 31/12/2020.

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2018/1258. (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

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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
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1.2. Suffix to the authorisation number

Number	1-4
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1.3. Product type(s)

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

2. META SPC 4 COMPOSITION

Status: Point in time view as at 31/12/2020.

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

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

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 4

Formulation	AL — Any other liquid
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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.

Status: Point in time view as at 31/12/2020.

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

	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 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

Status: Point in time view as at 31/12/2020.

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

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

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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
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*Status: Point in time view as at 31/12/2020.**Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Regulation (EU) 2018/1258. (See end of Document for details)*

	MEPA Soft Spray D ASTRI-UC SAC WINTERSPRAY				
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
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
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Status: Point in time view as at 31/12/2020.

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

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

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

Status: Point in time view as at 31/12/2020.

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

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

5. GENERAL DIRECTIONS FOR USE⁽⁶⁾ 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

Status: Point in time view as at 31/12/2020.

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

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: 18 months

6. OTHER INFORMATION

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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
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1.2. Suffix to the authorisation number

Status: Point in time view as at 31/12/2020.

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

Number	1-6
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1.3. Product type(s)

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

Status: Point in time view as at 31/12/2020.

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

	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**

Status: Point in time view as at 31/12/2020.

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

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

Status: Point in time view as at 31/12/2020.

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

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

Status: Point in time view as at 31/12/2020.

*Changes to legislation: There are currently no known outstanding effects for the
Commission Implementing Regulation (EU) 2018/1258. (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.

Status:

Point in time view as at 31/12/2020.

Changes to legislation:

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