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⁽¹⁾ Text with EEA relevance.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1991**of 27 November 2020****granting a Union authorisation for the biocidal product family ‘perform-IPA’****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 19 April 2016, Schuelke & Mayr GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘perform-IPA’ of product-types 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Germany had agreed to evaluate the application. The application was recorded under case number BC-AB023095-72 in the Register for Biocidal Products.
- (2) ‘perform-IPA’ contains propan-2-ol, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 27 August 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 7 April 2020, the Agency submitted to the Commission an opinion ⁽²⁾, the draft summary of the biocidal product characteristics (‘SPC’) of ‘perform-IPA’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘perform-IPA’ is a biocidal product family within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 27 April 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘perform-IPA’.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 5 March 2020 on the Union authorisation of ‘perform-IPA’ (ECHA/BPC/245/2020), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>

- (8) According to the opinion of the Agency, as regards the non-active substance diethyl phthalate contained in 'perform-IPA', it was not possible to conclude whether it meets the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ⁽³⁾ within the period for the evaluation of the application. Further examination of diethyl phthalate should therefore take place. If it is concluded that diethyl phthalate is considered as having endocrine-disrupting properties, the Commission will consider whether to cancel or amend the Union authorisation for 'perform-IPA' in accordance with Article 48 of Regulation (EU) No 528/2012.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0023656-0000 is granted to Schuelke & Mayr GmbH for the making available on the market and use of the biocidal product family 'perform-IPA' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 27 December 2020 until 30 November 2030.

Article 2

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

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

Done at Brussels, 27 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

ANNEX

Summary of product characteristics for a biocidal product family

perform-IPA

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0023656-0000

R4BP asset number: EU-0023656-0000

PART I

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

Name	perform-IPA
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1.2. Product type(s)

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Schülke & Mayr GmbH
	Address	Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Authorisation number	EU-0023656-0000	
R4BP asset number	EU-0023656-0000	
Date of the authorisation	27 December 2020	
Expiry date of the authorisation	30 November 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Schülke & Mayr GmbH
Address of manufacturer	Robert-Koch-Str. 2, 22851 Norderstedt, Germany
Location of manufacturing sites	Robert-Koch-Str. 2, 22851 Norderstedt, Germany

Name of manufacturer	BOCHEMIE a.s.
Address of manufacturer	Lidická 326, 735 95 Bohumín Czech Republic
Location of manufacturing sites	Lidická 326, 735 95 Bohumín Czech Republic

Name of manufacturer	Imeco
Address of manufacturer	Boschstr. 5, 63768 Hösbach Germany
Location of manufacturing sites	Boschstr. 5, 63768 Hösbach Germany Neue Straße 2-4, 09471 Königswalde Germany

Name of manufacturer	Tristel Solutions Limited
Address of manufacturer	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom
Location of manufacturing sites	Lynx Business Park, Fordham Road, Snailwell, CB8 7NY Cambridgeshire United Kingdom

Name of manufacturer	Techtex
Address of manufacturer	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom
Location of manufacturing sites	Units 7&8 Rhodes Bus. Park Silburn Way, M24 4NE Middleton United Kingdom

Name of manufacturer	A.F.P. GmbH
Address of manufacturer	Otto Brenner Straße 16, 21337 Lüneburg Germany
Location of manufacturing sites	Otto Brenner Straße 16, 21337 Lüneburg Germany

Name of manufacturer	Innovate GmbH
Address of manufacturer	Am Hohen Stein 11, 06618 Naumburg (Saale) Germany
Location of manufacturing sites	Am Hohen Stein 11, 06618 Naumburg (Saale) Germany

Name of manufacturer	Lysoform Dr. Hans Rosemann GmbH
Address of manufacturer	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany
Location of manufacturing sites	Kaiser-Wilhelm-Straße 133, 12247 Berlin Germany

Name of manufacturer	Sterisol AB
Address of manufacturer	Kronoängsgatan 3, 592 23 Vadstena Sweden
Location of manufacturing sites	Kronoängsgatan 3, 592 23 Vadstena Sweden

Name of manufacturer	Rudolf Dankwardt GmbH
Address of manufacturer	Gutenbergring 50-52, 22848 Norderstedt Germany
Location of manufacturing sites	Gutenbergring 50-52, 22848 Norderstedt Germany Lagerstr. 15, 19249 Jessenitz - Werk / Lübtheen Germany

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

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH (formerly Sasol)
Address of manufacturer	Römerstraße 733, 47443 Moers Germany
Location of manufacturing sites	Römerstraße 733, 47443 Moers Germany Shamrockstr. 88, 44643 Herne Germany

Active substance	Propan-2-ol
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	Postbus 2334, 3000 CH Rotterdam Netherlands
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., Vondelingenweg 601, 3196 KK Rotterdam-Pernis Netherlands

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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. Type(s) of formulation

Formulation(s)	Any other liquid (AL), ready-to-use Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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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 perform IPA liquid
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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)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents to /container to an approved waste disposal plant.

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

4.1. Use description

Table 1. Use # 1 – Disinfection of surfaces - spraying

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection after each production and cleaning process or when required according to standard operating procedure (SOP)
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: high-density polyethylene (HDPE), surlyn/polypropylene (PP) closure material is either: PP, polyoxymethylene (POM), low-density polyethylene (LDPE), HDPE, polyethylene (PE), ethylene-vinyl acetate (EVA), stainless steel, polybutylene terephthalate (PBT), (LD)PE, exp. polytetrafluoroethylene (PTFE), linear low density polyethylene (LLDPE), expanded PE (EXPPE), Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA

4.1.1. Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 minute.

4.1.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

-

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.

4.2. Use description

Table 2. Use # 2 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.2.1. *Use-specific instructions for use*

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.2.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

-

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.

4.3. Use description

Table 3. Use # 3 – disinfection of surfaces with food and feed contact - spraying

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.3.1. Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

-

4.3.5. *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.

4.4. Use description

Table 4. Use # 4 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD)PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP. canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA.

4.4.1. Use-specific instructions for use

Spray ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

-

4.4.5. *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.

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

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m².

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

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

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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)	perform® sterile alcohol IPA perform® classic alcohol IPA buraton® IPA perform® advanced alcohol IPA arcana® IPA clear IPA pure IPA disinfectant IPA Surface disinfection liquid classic sterile IPA mikrozid® sterile liquid Surface disinfection liquid sterile BTS 6000				
Authorisation number	EU-0023656-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	meta SPC 2 perform wipes IPA
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.

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

4.1. Use description

Table 5. Use # 1 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; biaxially oriented polypropylene (BOPP) + cast polypropylene (CPP) Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

-

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.

4.2. Use description

Table 6. Use # 2 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection after each production and cleaning process or when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE 3385

4.2.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.2.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

-

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.

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

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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

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)	perform classic wipes IPA buraton® wipes IPA perform® advanced wipes IPA arcana® wipes IPA clear IPA wipes pure IPA wipes disinfectant IPA wipes Surface disinfection wipes classic perform® sterile wipes IPA sterile IPA wipes mikrozid® sterile wipes Surface disinfection wipes sterile				
Authorisation number	EU-0023656-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 31. **META SPC 3 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3 mikrozid liquid
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1.2. **Suffix to the authorisation number**

Number	1-3
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.

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

4.1. Use description

Table 7. Use # 1 – Disinfection of surfaces - spraying

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)	Spraying Product will be sprayed directly on the surface
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD) PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure : PP/Silicone/EVA

4.1.1. *Use-specific instructions for use*

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 minute.

4.1.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

-

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.

4.2. **Use description**

Table 8. Use # 2 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algicides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD) PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure : PP/Silicone/EVA

4.2.1. Use-specific instructions for use

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.2.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

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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.

4.3. Use description

Table 9. Use # 3 – disinfection of surfaces with food and feed contact - spraying

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -

Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD) PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA Closure : PP/Silicone/EVA

4.3.1. Use-specific instructions for use

Spray ready-to-use product on the surface and allow to take effect at room temperature (20± 2°C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

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4.3.5. 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.

4.4. Use description

Table 10. Use # 4 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: -

	Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be sprayed or poured on the surface and wiped afterwards or the wipe will be wetted by spraying or pouring with the product and thereafter the product should be wiped on surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² . Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 250-1000 ml packaging material: HDPE, surlyn/PP closure material is either: PP, POM, LDPE, HDPE, PE, EVA, stainless steel, PBT, (LD) PE, exp. PTFE, LLDPE, EXPPE, Co Polymer PP canister: 5-10 L packaging material: HDPE. closure material is either: HDPE/LDPE Revolver BAG: 1 L packaging material: EVA closure material: PP/Silicone/EVA

4.4.1. *Use-specific instructions for use*

Spray or pour ready-to-use product on the surface and wipe afterwards or wet a wipe with the ready-to-use product by spraying or pouring and thereafter wipe the surface. Allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

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4.4.5. *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.

5. **GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 3**

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m².

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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)	mikrozyd® classic liquid mikrozyd® IPA liquid Surface Disinfection liquid pure				
Authorisation number	EU-0023656-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 4**1. META SPC 4 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 4 identifier**

Identifier	meta SPC 4 mikrozid wipes
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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)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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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 (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection.

	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents / container to an approved waste disposal plant.
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4. AUTHORISED USE(S) OF THE META SPC 4

4.1. Use description

Table 11. Use # 1 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algicides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

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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.

4.2. Use description

Table 12. Use # 2 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes Disinfection when required according to SOP.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20±2°C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

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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.

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

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

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)	mikrozid® classic wipes mikrozid® IPA wipes surface disinfection wipes classic				
Authorisation number	EU-0023656-0004 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 51. **META SPC 5 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5 kodan wipes IPA pro
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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)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.

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

4.1. Use description

Table 13. Use # 1 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

-

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.

4.2. **Use description**

Table 14. Use # 2 – disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE 3385

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

-

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.

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

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

-

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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)	kodan® wipes pure schülke® classic wipes				
Authorisation number	EU-0023656-0005 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 6 identifier

Identifier	meta SPC 6 kodan wipes IPA
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1.2. Suffix to the authorisation number

Number	1-6
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (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
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

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

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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3. **HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6**

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.

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

4.1. Use description

Table 15. Use # 1 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.1.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

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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.

4.2. Use description

Table 16. Use # 2 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria including <i>Mycobacterium tuberculosis</i> Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional General public (non-professional)
Pack sizes and packaging material	Soft pack: 1-200 wipes Packaging material: LDPE/Alu/PET; LDPE/PET; BOPP+CPP Pouch: 10-200 wipes Packaging material: LDPE/PET Tube: 50-200 wipes Packaging material: HDPE closure material is either PP, PE3385

4.2.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20±2°C).

4.2.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

-

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.

5. GENERAL DIRECTIONS FOR USE ⁽⁹⁾ OF THE META SPC 6

5.1. Instructions for use

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. Risk mitigation measures

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of the reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

-

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

⁽⁹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

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)	schülke Hygiene-Tücher SOS Desinfizierende Feuchttücher SOS Hygiene-Tücher kodan® clean comfort wipes schülke clean comfort wipes Hygiene-Tücher Desinfizierende Feuchttücher Desinfektionstücher clean comfort wipes disinfecting wipes				
Authorisation number	EU-0023656-0006 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 71. **META SPC 7 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 7 identifier**

Identifier	meta SPC 7 AntiLy SD
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1.2. **Suffix to the authorisation number**

Number	1-7
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1.3. **Product type(s)**

Product type(s)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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2. **META SPC 7 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. Type(s) of formulation of the meta SPC 7

Formulation(s)	Any other liquid (AL), ready-to-use
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. Use description

Table 17. Use # 1 – Disinfection of surfaces - spraying

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)

Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² .
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP; Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

4.1.1. Use-specific instructions for use

Spray ready-to-use product onto the surfaces and allow to take effect for at least 1 minute at room temperature (20±2 °C).

4.1.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

-

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.

4.2. Use description

Table 18. Use # 2 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).

Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² .
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel); Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

4.2.1. Use-specific instructions for use

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20±2 °C).

4.2.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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.

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

-

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.

4.3. Use description

Table 19. Use # 3 – Disinfection of surfaces with food and feed contact - spraying

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)

Application method(s)	Spraying Product will be sprayed directly on the surface.
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² .
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil)

4.3.1. Use-specific instructions for use

Spray ready-to-use product onto the surface and allow to take effect at room temperature (20 ± 2 °C) for at least 1 (bactericidal and yeasticidal activity) or 2 minutes (virucidal activity).

4.3.2. Use-specific risk mitigation measures

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

-

4.3.5. 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.

4.4. Use description

Table 20. Use # 4 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)

Application method(s)	Wiping Product is applied on wipes by pouring, spraying or soaking and the surface is thoroughly wiped with the soaked wipe afterwards (wet-wiping).
Application rate(s) and frequency	Ready-to-use. Do not apply more than 25 ml/m ² .
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Bottle: 125-1000 ml packaging material: HDPE Clack cap material: PP Fine mist-sprayer: complex system (PE-LD, PP, PBT, POM, EVA, stainless steel) Spray head: complex system (PP, PE, POM, Synthetic oil, Silicon oil) Canister: 5-30 L packaging material: HDPE closure material: HDPE

4.4.1. *Use-specific instructions for use*

Apply the ready-to-use product on wipes by pouring, spraying or soaking and wipe the surface thoroughly with the wet wipe (wet-wiping). Allow to take effect for at least 5 minutes at room temperature (20 ± 2°C).

4.4.2. *Use-specific risk mitigation measures*

The following personal risk mitigation measure can be applied for disinfection of food processing machinery and for refilling procedure unless it can be replaced by technical and/or organisational measures: Wear eye protection during handling of the product.

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

See general directions for use.

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

-

4.4.5. *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.

5. **GENERAL DIRECTIONS FOR USE ⁽⁷⁾ OF THE META SPC 7**

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Do not apply more than 25 ml/m².

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Apply a funnel for refilling.

⁽⁷⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

-

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

Shelf-life: 36 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. OTHER INFORMATION

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

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

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

Trade name(s)	AntiLy 5				
Authorisation number	EU-0023656-0007 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

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

Trade name(s)	AntiLy 6				
Authorisation number	EU-0023656-0008 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

META SPC 8**1. META SPC 8 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 8 identifier**

Identifier	meta SPC 8 AntiLy SD wipes
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1.2. Suffix to the authorisation number

Number	1-8
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1.3. Product type(s)

Product type(s)	PT04 - Food and feed area (Disinfectants) PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
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2. META SPC 8 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 8**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1	63,1

2.2. Type(s) of formulation of the meta SPC 8

Formulation(s)	Any other liquid (AL), ready-to-use, wipes impregnated with disinfectant formulation
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground and bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment. Use non-sparking tools. Take action to prevent static discharges. Avoid breathing vapours. Avoid breathing spray. Use only outdoors or in a well-ventilated area. Wear eye protection.

	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor if you feel unwell. If eye irritation persists: Get medical advice. If eye irritation persists: Get medical attention. In case of fire: Use alcohol-resistant foam, carbon dioxide or water mist to extinguish. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of contents /container to an approved waste disposal plant.
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4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 21. Use # 1 – Disinfection of surfaces - wiping

Product type	PT02 - Disinfectants and algacides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces such as small work surfaces in medical and non-medical areas as well as surfaces in cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

4.1.1. Use-specific instructions for use

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20± 2°C).

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

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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.

4.2. Use description

Table 22. Use # 2 – Disinfection of surfaces with food and feed contact - wiping

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: Bacteria Common name: - Development stage: - Scientific name: Yeast Common name: - Development stage: - Scientific name: Viruses Common name: - Development stage: -
Field(s) of use	Indoor Disinfection of clean non-porous surfaces in kitchens and food industry including cleanrooms (class A/B)
Application method(s)	Wiping Product will be wiped directly on the surface.
Application rate(s) and frequency	Ready-to-use wipes
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Can: 100-150 wipes Packaging: HDPE Closure material: HDPE Pack: 100-150 wipes Packaging: PET/PE

4.2.1. *Use-specific instructions for use*

Thoroughly wipe the surface with the wipe and allow to take effect for at least 5 minutes at room temperature (20±2°C).

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

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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.

5. **GENERAL DIRECTIONS FOR USE ⁽⁸⁾ OF THE META SPC 8**

5.1. **Instructions for use**

Clean the surface carefully before use.

Remove excess water from the surface before disinfection, if appropriate.

Make sure to wet surfaces completely.

Used wipes must be disposed in a closed container.

5.2. **Risk mitigation measures**

The product must only be applied for disinfection of small surfaces.

Ensure adequate ventilation to prevent the formation of explosive atmospheres.

Avoid contact with eyes.

Keep out of reach of children and pets.

Keep children and pets away from rooms where disinfection is taking place. Provide adequate ventilation before children and pets enter treated rooms. This does not apply to hospital patient rooms.

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

First aid:

In case of accident: Call a poison centre or a doctor.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

If on skin: Wash with water. If skin irritation occurs: Get medical advice.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

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

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

Shelf-life: 24 months

Keep container tightly closed.

Store in a well-ventilated place.

Protect from sunlight.

Store at room temperature in the original container.

6. **OTHER INFORMATION**

The product contains propan-2-ol (CAS No.: 67-63-0), for which a European reference value of 129,28 mg/m³ for the professional user was agreed and used for the risk assessment of the product.

⁽⁸⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	AntiLy 5 wipes				
Authorisation number	EU-0023656-0009 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

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

Trade name(s)	AntiLy 6 wipes				
Authorisation number	EU-0023656-0010 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,1

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1992**of 2 December 2020****amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/EC ⁽¹⁾, and in particular Article 4(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 474/2006 ⁽²⁾ establishes the list of air carriers, which are subject to an operating ban within the Union.
- (2) Certain Member States and the European Union Aviation Safety Agency ('the Agency') communicated to the Commission, pursuant to Article 4(3) of Regulation (EC) No 2111/2005, information that is relevant for updating that list. Third countries and international organisations also provided relevant information. The information provided contributes to the determination that the list should be updated.
- (3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations which would form the basis of a decision to impose an operating ban on them within the Union or to modify the conditions of an operating ban imposed on an air carrier which is included in the list in Annex A or B to Regulation (EC) No 474/2006.
- (4) The Commission gave the air carriers concerned the opportunity to consult all relevant documentation, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Regulation (EC) No 2111/2005 (the 'EU Air Safety Committee').
- (5) The Commission has informed the EU Air Safety Committee about the ongoing joint consultations, within the framework of Regulation (EC) No 2111/2005 and Commission Regulation (EC) No 473/2006 ⁽³⁾, with the competent authorities and air carriers of Belarus, the Dominican Republic, Kazakhstan, Moldova, Pakistan and Russia. The Commission also informed the EU Air Safety Committee about the aviation safety situation in Armenia, Congo (Brazzaville), Equatorial Guinea, Indonesia and Kyrgyzstan.
- (6) The Agency informed the Commission and the EU Air Safety Committee about the technical assessments conducted for the initial evaluation and the continuous monitoring of third country operator ('TCO') authorisations, issued pursuant to Commission Regulation (EU) No 452/2014 ⁽⁴⁾.

⁽¹⁾ OJ L 344, 27.12.2005, p. 15.

⁽²⁾ Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).

⁽³⁾ Commission Regulation (EC) No 473/2006 of 22 March 2006 laying down implementing rules for the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 8).

⁽⁴⁾ Commission Regulation (EU) No 452/2014 of 29 April 2014 laying down technical requirements and administrative procedures related to air operations of third country operators pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 133, 6.5.2014, p. 12).

- (7) The Agency also informed the Commission and the EU Air Safety Committee about the results of the analysis of ramp inspections stemming from the Safety Assessment of Foreign Aircraft ('SAFA') carried out under the EU Ramp Inspection Programme as provided for in Commission Regulation (EU) No 965/2012 ⁽⁵⁾.
- (8) In addition, the Agency informed the Commission and the EU Air Safety Committee about the technical assistance projects carried out in third countries affected by an operating ban under Regulation (EC) No 474/2006. Furthermore, the Agency provided information on the plans and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities in third countries with a view to helping them resolve non-compliance with applicable international civil aviation safety standards. Member States were invited to respond to such requests on a bilateral basis in coordination with the Commission and the Agency. In that regard, the Commission reiterated the usefulness of providing information to the international aviation community, particularly through the International Civil Aviation Organisation's ('ICAO') Aviation Safety Implementation Assistance Partnership tool, on technical assistance to third countries provided by the Union and Member States to improve aviation safety around the world.
- (9) Eurocontrol provided the Commission and the EU Air Safety Committee with an update on the status of the SAFA and TCO alarming functions, including statistics about alert messages for banned air carriers.

Union air carriers

- (10) Following the Agency's analysis of information resulting from ramp inspections carried out on the aircraft of Union air carriers, as well as standardisation inspections carried out by the Agency, complemented also with information stemming from specific inspections and audits carried out by national aviation authorities, several Member States have taken certain enforcement measures and informed the Commission and the EU Air Safety Committee about those measures.
- (11) Member States reiterated their readiness to act as necessary in the event that the relevant safety information indicates imminent safety risks as a consequence of a lack of compliance by Union air carriers with the relevant safety standards.

Air carriers from Belarus

- (12) Air carriers from Belarus have never been included in Annex A or B to Regulation (EC) No 474/2006.
- (13) The Commission continued monitoring the progress of the competent authority of Belarus, namely the Aviation Department of Belarus ('AD-BLR') in strengthening its capabilities to ensure that operations by air carriers certified in Belarus are conducted in accordance with international safety standards.
- (14) On 8 October 2020, the Commission, the Agency and representatives of AD-BLR held a technical meeting to discuss the actions undertaken by AD-BLR, including those addressing the Agency's safety concerns identified during its technical assessments conducted for the initial evaluation and the continuous monitoring of TCO authorisations pursuant to Commission Regulation (EU) No 452/2014.
- (15) During that meeting, AD-BLR provided information on its new organizational structure, including the recruitment and training of the staff, the functioning of its quality department, the status of the recertification of air carriers certified by AD-BLR and the temporary limitations it imposed to some air carriers, as well as the activities conducted as part of its surveillance program. AD-BLR also noted that the implementation of the corrective action plan developed in response to the deficiencies identified during the Union on-site assessment visit of March 2019 was completed.

⁽⁵⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

- (16) On 17 November 2020, the Commission informed the EU Air Safety Committee about explanations provided by AD-BLR. On this basis, even if there are some deficiencies with regard to certain air carriers certified by AD-BLR that need rectification, such as the failure to adapt the maintenance program to the type of operations of the aircraft, or deficiencies identified in the management of hard time and life time components, they do not warrant the inclusion of those air carriers in Annex A to Regulation (EC) No 474/2006.
- (17) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage with respect to air carriers from Belarus there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (18) Member States should continue verifying the effective compliance of air carriers certified in Belarus with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (19) Where any relevant safety information reveals imminent safety risks as a consequence of a lack of compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from the Dominican Republic

- (20) Air carriers from the Dominican Republic have never been included in Annex A or B to Regulation (EC) No 474/2006.
- (21) A Union on-site assessment visit was conducted from 27 to 31 January 2020 by representatives of the Commission, the Agency and Member States in the Dominican Republic at the offices of the Instituto Dominicano de Aviación Civil ("IDAC"). Whereas the results of that visit showed that IDAC had the capabilities to oversee the aviation activities in the Dominican Republic, a number of weaknesses in the safety oversight system were identified. Those weaknesses however do not raise immediate safety concerns. IDAC developed a corrective action plan to address the shortcomings identified and sent it to the Commission on 15 April 2020.
- (22) On 4 November 2020, IDAC provided a progress report on the implementation of its corrective action plan. That progress report provided detailed information for each shortcoming identified, such as the root cause analysis, the corrective action being implemented and its progress, the different tasks of each action and their progress, as well as a detailed follow-up. IDAC estimates that the completion of its corrective action plan stands at 87,66 %.
- (23) Based on this report, the Commission considers that at this stage IDAC has the necessary ability and willingness to address the safety deficiencies identified during the visit, and that it is effectively implementing its action plan. On those grounds, there was no need for a hearing of IDAC before the EU Air Safety Committee.
- (24) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage with respect to air carriers from the Dominican Republic there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (25) Member States should continue verifying the effective compliance of air carriers certified in the Dominican Republic with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (26) Where any relevant safety information reveals imminent safety risks as a consequence of a lack of compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Kazakhstan

- (27) Air carriers from Kazakhstan were removed from Annex A to Regulation (EC) No 474/2006 in 2016 ⁽⁶⁾.
- (28) In February 2020, due to an apparent decline in the safety oversight by the competent authorities in Kazakhstan, the Commission opened consultations pursuant to Article 3(2) of Regulation (EC) No 473/2006. The EU Air Safety Committee was provided with an overview of the safety oversight situation in Kazakhstan at its meeting in May 2020.
- (29) As a follow up to the EU Air Safety Committee's May 2020 meeting, the Commission and the Agency have maintained a continuous contact with the Civil Aviation Committee of Kazakhstan ('CAC KZ') and the Aviation Administration of Kazakhstan Joint Stock Company ('AAK') to gather further data and information. In particular, the Commission has asked about the revocation by the AAK of the Air Operator Certificate ('AOC') of *Sigma Airlines* on safety grounds.
- (30) On 16 October 2020 a meeting between the Commission, the Agency, Member States and representatives from the CAC KZ and from the AAK took place. AAK provided a comprehensive overview of its functions, of its conduct of safety oversight, including an update with respect to the list of AOC holders, registered aircraft, accidents, serious incidents and aviation occurrences and its enforcement measures. It also provided an overview of its surveillance activities, its plans as regards the recruitment and training of technical personnel, and its strategic approach to technical development within the context of aviation safety capacity building. Furthermore, the AAK informed about development of additional oversight procedures, enhanced implementation of the safety oversight programme and steps taken for the implementation of a quality management system.
- (31) The AAK explained that, together with CAC KZ, it takes actions to improve safety oversight in Kazakhstan, including the necessary modification of the national legal framework, which should lead to a better functional separation between the two competent aviation authorities (AAK and CAC KZ).
- (32) Based on the information currently available, including the Agency's TCO authorisation assessments and the information provided by the AAK, both prior to and during the meeting of 16 October 2020, it appears that significant efforts and consequential developments are being made to address the safety situation in Kazakhstan. The Commission, whilst acknowledging the action taken to date, will continue its monitoring and assessment of how the situation develops further. In this context, the Commission intends to carry out, with the assistance of the Agency and Member States, a Union on-site assessment visit to Kazakhstan.
- (33) In view of the aforementioned evidence of the actions undertaken by the AAK and the CAC KZ, and in accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage with respect to air carriers from Kazakhstan, there are no grounds for amending the list of air carriers which are subject to an operating ban within the Union.
- (34) Member States should continue verifying the effective compliance of air carriers certified in Kazakhstan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (35) Where any relevant safety information reveals imminent safety risks as a consequence of a lack of compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Moldova

- (36) Air carriers from Moldova, except for three air carriers *Air Moldova*, *Fly One* and *Aerotranscargo*, were included in Annex A to Regulation (EC) No 474/2006 in 2019 ⁽⁷⁾.

⁽⁶⁾ Commission Implementing Regulation (EU) 2016/2214 of 8 December 2016 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union (OJ L 334, 9.12.2016, p. 6).

⁽⁷⁾ Commission Implementing Regulation (EU) 2019/618 of 15 April 2019 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union, (OJ L 106, 17.4.2019, p. 1).

- (37) On 23 July 2020, at Moldova's request and as part of continuous monitoring activities, the Commission and representatives of the Civil Aviation Authority of Moldova ('CAAM') held a meeting, during which the CAAM provided an overview of its functions, including the basic principles of its conduct of safety oversight. Other information provided by the CAAM included an overview of developments and state-of-play of their corrective action plan addressing the observations and recommendations resulting from the Union on-site assessment visit in February 2019.
- (38) Furthermore, on 31 July 2020, as a follow-up to the technical meeting, the CAAM provided additional information on the progress made with regard to the corrective action plan addressing the safety deficiencies identified during the Union on-site assessment visit. On the basis of information provided it seems that the CAAM has made some progress in the implementation of international safety standards. However, currently there is not enough evidence justifying lifting the operational restrictions on air carriers from Moldova. The provided information about the improvements should be further verified, preferably during a Union on-site assessment visit to Moldova.
- (39) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage with respect to air carriers from Moldova there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union.
- (40) Member States should continue verifying the effective compliance of air carriers certified in Moldova with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (41) Where any relevant safety information reveals imminent safety risks as a consequence of a lack of compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Pakistan

- (42) *Pakistan International Airlines* was included in Annex B to Regulation (EC) No 474/2006 in March 2007 ⁽⁸⁾ and removed in November 2007 ⁽⁹⁾.
- (43) On 24 June 2020, a statement from the Pakistan Federal Minister for Aviation revealed that a high number of the pilot licenses, issued by the Pakistan Civil Aviation Authority ('PCAA'), were obtained by fraudulent means.
- (44) This event, and considering also a lack of effective implementation of a Safety Management System ('SMS'), has led the Agency to suspend the TCO authorisations of *Pakistan International Airlines* and *Vision Air* with effect from 1 July 2020. The apparent lack of effective oversight by the PCAA in accordance with international safety standards contributed to that decision.
- (45) On 1 July 2020, the Commission opened consultations with PCAA pursuant to Article 3(2) of Regulation (EC) No 473/2006. The Commission requested PCAA to provide information about its response to the Federal Minister's statement. In particular, the Commission requested information about the oversight of Pakistan registered air carriers, including their Safety Management Systems, as well as the evidence that a similar situation does not take place in other sectors, such as cabin crew certification or the licensing of maintenance engineers.
- (46) On 9 July and 25 September 2020, technical meetings were held with PCAA to discuss the information provided and the actions taken.
- (47) PCAA has been cooperative and transparent in its dealings with the Commission. It informed the Commission that its examination of the situation ultimately led to the revocation or suspension of the fraudulent licenses, as well as to the decision to stop issuing new licenses as from the end of June 2020. PCAA also informed that new aviation

⁽⁸⁾ Commission Regulation (EC) No 235/2007 of 5 March 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 66, 6.3.2007, p. 3).

⁽⁹⁾ Commission Regulation (EC) No 1400/2007 of 28 November 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 311, 29.11.2007, p. 12).

rules had been put in place to deal with the issues raised and, where appropriate, enforcement actions had been taken. With regard to the SMS oversight, PCAA admitted that its implementation is in early stages. It appears that PCAA still needs to effectively identify the root causes of its problems, and to deal with them in a sustainable manner.

- (48) Based on the information currently available, including the Agency's TCO authorisation assessment information, it is apparent that PCAA is engaged in a significant effort to enact the corrective actions needed to address the identified safety situation in Pakistan. The Commission, whilst acknowledging the actions taken to date, will continue its monitoring and assessment of how the situation develops further. In this context, the Commission intends to carry out, with the assistance of the Agency and Member States, a Union on-site assessment visit to Pakistan.
- (49) In view of the aforementioned evidence of the actions undertaken by PCAA and in accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage with respect to air carriers from Pakistan there are no grounds for amending the list of air carriers which are subject to an operating ban within the Union.
- (50) Member States should continue verifying the effective compliance of air carriers certified in Pakistan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.
- (51) Where any relevant safety information reveals imminent safety risks as a consequence of a lack of compliance with international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Russia

- (52) The Commission, the Agency and the competent authorities of the Member States have continued to closely monitor the safety performance of air carriers certified in Russia and operating within the Union, including through prioritisation of the ramp inspections carried out on certain Russian air carriers in accordance with Regulation (EU) No 965/2012.
- (53) On 22 October 2020, representatives of the Commission and the Agency met with representatives of the Russian Federal Air Transport Agency ('FATA') to review the safety performance of air carriers certified in Russia on the basis of reports of ramp inspections carried out in the period between 15 April 2019 and 15 October 2020, and to identify in which cases FATA should strengthen its oversight activities.
- (54) The review of the SAFA ramp inspections of air carriers certified in Russia did not reveal any significant or recurrent safety deficiency.
- (55) Based on the information currently available, including information provided by FATA at the meeting, the Commission considers that at this stage FATA has the necessary ability and willingness to address safety deficiencies. On those grounds, there was no need for a hearing of the Russian aviation authorities or of any air carriers certified in Russia before the EU Air Safety Committee.
- (56) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission therefore considers that at this stage there are no grounds for amending the list of air carriers which are subject to an operating ban within the Union by including air carriers from Russia.
- (57) Member States should keep verifying effective compliance with the relevant international safety standards by certain air carriers from Russia, through prioritisation of ramp inspections in accordance with Regulation (EU) No 965/2012.
- (58) Where those inspections detect an imminent safety risk as a consequence of non-compliance with international safety standards, the Commission can impose an operating ban on the Russian certified air carriers concerned and include them in Annex A or Annex B to Regulation (EC) No 474/2006.
- (59) Regulation (EC) No 474/2006 should therefore be amended accordingly.

- (60) Articles 5 and 6 of Regulation (EC) No 2111/2005 recognise the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and the traveling public, that the decisions in the context of updating the list of air carriers which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.
- (61) The measures provided for in this Regulation are in accordance with the opinion of the EU Air Safety Committee established by Regulation (EC) No 2111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

- (1) Annex A is replaced by the text in Annex I to this Regulation;
- (2) Annex B is replaced by the text in Annex II to this Regulation.

Article 2

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

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

Done in Brussels, 2 December 2020.

*For the Commission,
On behalf of the president,
Adina VĂLEAN
Member of the Commission*

ANNEX I

ANNEX A

LIST OF AIR CARRIERS WHICH ARE BANNED FROM OPERATING WITHIN THE UNION, WITH EXCEPTIONS ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
AVIOR AIRLINES	ROI-RNR-011	ROI	Venezuela
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname
IRAN ASEMAN AIRLINES	FS-102	IRC	Iran
IRAQI AIRWAYS	001	IAW	Iraq
MED-VIEW AIRLINE	MVA/AOC/10-12/05	MEV	Nigeria
AIR ZIMBABWE (PVT)	177/04	AZW	Zimbabwe
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			Afghanistan
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Afghanistan
KAM AIR	AOC 001	KMF	Afghanistan
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of TAAG Angola Airlines and Heli Malongo, including			Angola
AEROJET	AO-008/11-07/17 TEJ	TEJ	Angola
GUICANGO	AO-009/11-06/17 YYY	Unknown	Angola
AIR JET	AO-006/11-08/18 MBC	MBC	Angola
BESTFLYA AIRCRAFT MANAGEMENT	AO-015/15-06/17YYY	Unknown	Angola
HELIANG	AO 007/11-08/18 YYY	Unknown	Angola
SJL	AO-014/13-08/18YYY	Unknown	Angola
SONAIR	AO-002/11-08/17 SOR	SOR	Angola
All air carriers certified by the authorities with responsibility for regulatory oversight of Armenia, including			Armenia
AIRCOMPANY ARMENIA	AM AOC 065	NGT	Armenia
ARMENIA AIRWAYS	AM AOC 063	AMW	Armenia
ARMENIAN HELICOPTERS	AM AOC 067	KAV	Armenia

⁽¹⁾ Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
ATLANTIS ARMENIAN AIRLINES	AM AOC 068	AEU	Armenia
ATLANTIS EUROPEAN AIRWAYS	AM AOC 017	LUR	Armenia
MARS AVIA	AM AOC 066	MRS	Armenia
SKYBALL	AM AOC 069	N/A	Armenia
All air carriers certified by the authorities with responsibility for regulatory oversight of Congo (Brazzaville), including			Congo (Brazzaville)
CANADIAN AIRWAYS CONGO	CG-CTA 006	Unknown	Congo (Brazzaville)
EQUAFLIGHT SERVICES	CG-CTA 002	EKA	Congo (Brazzaville)
EQUAJET	RAC06-007	EKJ	Congo (Brazzaville)
TRANS AIR CONGO	CG-CTA 001	TSG	Congo (Brazzaville)
SOCIETE NOUVELLE AIR CONGO	CG-CTA 004	Unknown	Congo (Brazzaville)
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of Congo (DRC), including			Democratic Republic of Congo (DRC)
AIR FAST CONGO	AAC/DG/OPS-09/03	Unknown	Democratic Republic of Congo (DRC)
AIR KATANGA	AAC/DG/OPS-09/08	Unknown	Democratic Republic of Congo (DRC)
BUSY BEE CONGO	AAC/DG/OPS-09/04	Unknown	Democratic Republic of Congo (DRC)
COMPAGNIE AFRICAINE D'AVIATION (CAA)	AAC/DG/OPS-09/02	Unknown	Democratic Republic of Congo (DRC)
CONGO AIRWAYS	AAC/DG/OPS-09/01	Unknown	Democratic Republic of Congo (DRC)
KIN AVIA	AAC/DG/OPS-09/10	Unknown	Democratic Republic of Congo (DRC)
MALU AVIATION	AAC/DG/OPS-09/05	Unknown	Democratic Republic of Congo (DRC)
SERVE AIR CARGO	AAC/DG/OPS-09/07	Unknown	Democratic Republic of Congo (DRC)
SWALA AVIATION	AAC/DG/OPS-09/06	Unknown	Democratic Republic of Congo (DRC)

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
MWANT JET	AAC/DG/OPS-09/09	Unknown	Democratic Republic of Congo (RDC)
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			Djibouti
DAALLO AIRLINES	Unknown	DAO	Djibouti
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			Equatorial Guinea
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/DGAC/SOPS	CEL	Equatorial Guinea
Cronos AIRLINES	2011/0004/MTTCT/DGAC/SOPS	Unknown	Equatorial Guinea
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			Eritrea
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of Kyrgyzstan, including			Kyrgyzstan
AIR COMPANY AIR KG	50	Unknown	Kyrgyzstan
AIR MANAS	17	MBB	Kyrgyzstan
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyzstan
SKY KG AIRLINES	41	KGK	Kyrgyzstan
TEZ JET	46	TEZ	Kyrgyzstan
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			Liberia
All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			Libya
AFRIQIYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
AL MAHA AVIATION	030/18	Unknown	Libya

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
BURQA AIR	002/01	BRQ	Libya
GLOBAL AVIATION AND SERVICES	008/05	GAK	Libya
LIBYAN AIRLINES	001/01	LAA	Libya
LIBYAN WINGS AIRLINES	029/15	LWA	Libya
PETRO AIR	025/08	PEO	Libya
All air carriers certified by the authorities with responsibility for regulatory oversight of Moldova with the exception of Air Moldova, Fly One and Aerotranscarga, including			Moldova
Î.M "VALAN ICC" SRL	MD009	VLN	Moldova
CA "AIM AIR" SRL	MD015	AAM	Moldova
CA "AIR STORK" SRL	MD018	MSB	Moldova
Î M „ MEGAVIATION" SRL	MD019	ARM	Moldova
CA "PECOTOX-AIR" SRL	MD020	PXA	Moldova
CA "TERRA AVIA" SRL	MD022	TVR	Moldova
CA "FLY PR O" SRL	MD023	PVV	Moldova
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			Nepal
AIR DYNASTY HELI. S.	035/2001	Unknown	Nepal
ALTITUDE AIR	085/2016	Unknown	Nepal
BUDDHA AIR	014/1996	BHA	Nepal
FISHTAIL AIR	017/2001	Unknown	Nepal
SUMMIT AIR	064/2010	Unknown	Nepal
HELI EVEREST	086/2016	Unknown	Nepal
HIMALAYA AIRLINES	084/2015	HIM	Nepal
KAILASH HELICOPTER SERVICES	087/2018	Unknown	Nepal
MAKALU AIR	057A/2009	Unknown	Nepal
MANANG AIR PVT	082/2014	Unknown	Nepal
MOUNTAIN HELICOPTERS	055/2009	Unknown	Nepal
PRABHU HELICOPTERS	081/2013	Unknown	Nepal
NEPAL AIRLINES CORPORATION	003/2000	RNA	Nepal

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
SAURYA AIRLINES	083/2014	Unknown	Nepal
SHREE AIRLINES	030/2002	SHA	Nepal
SIMRIK AIR	034/2000	Unknown	Nepal
SIMRIK AIRLINES	052/2009	RMK	Nepal
SITA AIR	033/2000	Unknown	Nepal
TARA AIR	053/2009	Unknown	Nepal
YETI AIRLINES	037/2004	NYT	Nepal
All air carriers certified by the authorities with responsibility for regulatory oversight of Sao Tome and Principe, including			Sao Tome and Principe
AFRICA'S CONNECTION	10/AOC/2008	ACH	Sao Tome and Principe
STP AIRWAYS	03/AOC/2006	STP	Sao Tome and Principe
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone			Sierra Leone
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			Sudan
ALFA AIRLINES SD	54	AAJ	Sudan
BADR AIRLINES	35	BDR	Sudan
BLUE BIRD AVIATION	11	BLB	Sudan
ELDINDER AVIATION	8	DND	Sudan
GREEN FLAG AVIATION	17	GNF	Sudan
HELEJETIC AIR	57	HJT	Sudan
KATA AIR TRANSPORT	9	KTV	Sudan
KUSH AVIATION CO.	60	KUH	Sudan
NOVA AIRWAYS	46	NOV	Sudan
SUDAN AIRWAYS CO.	1	SUD	Sudan
SUN AIR	51	SNR	Sudan
TARCO AIR	56	TRQ	Sudan'

ANNEX II

‘ANNEX B

LIST OF AIR CARRIERS WHICH ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE UNION ⁽¹⁾

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate (“AOC”) Number	ICAO three letter designator	State of the Operator	Aircraft type restricted	Registration mark (s) and, when available, construction serial number(s) of restricted aircraft	State of registry
AIR SERVICE COMORES	06-819/TA-15/DGACM	KMD	Comoros	All fleet with the exception of: LET 410 UVP.	All fleet with the exception of: D6-CAM (851336).	Comoros
IRAN AIR	FS100	IRA	Iran	All aircraft of type Fokker F100 and of type Boeing B747	Aircraft of type Fokker F100 as mentioned on the AOC; aircraft of type Boeing B747 as mentioned on the AOC	Iran
AIR KORYO	GAC-AOC/KOR-01	KOR	North Korea	All fleet with the exception of: 2 aircraft of type TU- 204.	All fleet with the exception of: P-632, P-633.	North Korea’

⁽¹⁾ Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1993**of 4 December 2020****authorising the placing on the market of selenium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Commission Implementing Regulation (EU) 2019/760 ⁽³⁾ authorised, in accordance with Regulation (EU) 2015/2283, the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾, excluding food supplements for infants and young children.
- (4) On 21 September 2018, the company Skotan S.A. ('the applicant') introduced an application to the Commission pursuant to Article 10(1) of Regulation (EU) 2015/2283 to place selenium-enriched biomass of the yeast *Yarrowia lipolytica* on the Union market as a novel food. The applicant requested for selenium-enriched biomass of the yeast *Yarrowia lipolytica* to be used in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁵⁾. The maximum use levels proposed by the applicant are 0,2 g per day for children from 3 to 9 years of age, and 1 g per day for adolescents and adults.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 18 February 2019, asking it to provide a scientific opinion by carrying out an assessment for selenium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Commission Implementing Regulation (EU) 2019/760 of 13 May 2019 authorising the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 125, 14.5.2019, p. 13).

⁽⁴⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁵⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

- (6) On 18 December 2019, the Authority adopted the scientific opinion ‘Safety of selenium-enriched biomass of *Yarrowia lipolytica* as a novel food pursuant to Regulation (EU) 2015/2283’ ⁽⁶⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In that opinion, the Authority concluded that selenium-containing yeast (*Yarrowia lipolytica*) biomass is not of safety concern at the proposed use levels. The Authority also considered that the selenium provided by selenium-containing yeast (*Yarrowia lipolytica*) biomass is as safe as selenium from other dietary sources.
- (8) The Authority also noted that, at the use levels proposed by the applicant, the intake of the novel food in combination with a background diet high in selenium could lead to total selenium intakes exceeding the Tolerable Upper Intake Level (‘UL’) for selenium established by the Scientific Committee on Food ⁽⁷⁾, in all target population groups, except for children from 7 to 9 years of age.
- (9) In light of the observation made by the Authority relating to the combined intake of selenium, the applicant submitted a modified request to the Commission with regard to the conditions of use of selenium-containing yeast (*Yarrowia lipolytica*) biomass, in particular concerning the maximum levels of the novel food in food supplements and the population groups for which food supplements are intended. The applicant proposed the novel food to be used in food supplements intended for the general population from 4 years of age, at levels ranging from 50 mg/day to 800 mg/day, that would result in selenium intakes which, combined with the selenium intakes from a background diet high in selenium, would not exceed the UL for selenium.
- (10) The Commission considers that the Authority’s opinion and the modified conditions of use requested by the applicant give sufficient grounds to establish that selenium-containing yeast (*Yarrowia lipolytica*) biomass at the proposed uses and use levels when used in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (11) Regulation (EU) 2017/2470 should be therefore amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Selenium-containing yeast (*Yarrowia lipolytica*) biomass as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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

⁽⁶⁾ EFSA Journal 2020;18(1):5992.

⁽⁷⁾ SCF (Scientific Committee on Food), 2000. Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of selenium. SCF/CS/NUT/UPPLEV/25 Final, 18 pp.

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

Done at Brussels, 4 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Selenium-containing yeast (<i>Yarrowia lipolytica</i>) biomass	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "selenium-containing yeast (<i>Yarrowia lipolytica</i>) biomass". The labelling of food supplements containing selenium-containing yeast (<i>Yarrowia lipolytica</i>) biomass shall bear a statement that the food supplements should not be consumed by infants and children under 4 years of age/children under 7 years of age/children under 11 years of age/children and adolescents under 18 years of age (*).	
	Food supplements as defined in Directive 2002/46/EC ⁽¹⁾ , excluding food supplements for infants and children under 4 years of age	50 mg/day for children from 4 to 6 years of age, resulting in 10 µg of selenium per day 100 mg/day for children from 7 to 10 years of age, resulting in 20 µg of selenium per day 500 mg/day for adolescents from 11 to 17 years of age, resulting in 100 µg of selenium per day 800 mg/day for adults, resulting in 160 µg of selenium per day		

⁽¹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(*) Depending on the age group the food supplement is intended for.

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Selenium-containing yeast (<i>Yarrowia lipolytica</i>) biomass	Description/Definition: The novel food is the dried and heat-killed selenium-containing biomass of the yeast <i>Yarrowia lipolytica</i>. The novel food is produced by fermentation in the presence of sodium selenite followed by a number of purification steps including a heat-killing step of the yeast to ensure the absence of viable <i>Yarrowia lipolytica</i> cells in the novel food. Characteristics/Composition: Total selenium: 165–200 µg/g Se-methionine ⁽¹⁾: 100–140 µg/g Protein: 40–50 g/100 g Dietary fibre: 24–32 g/100 g Sugars: < 1 g/100 g Fat: 6–12 g/100 g Total ash: ≤ 15 % Water: ≤ 5 % Dry matter: ≥ 95 % Heavy metals: Lead: ≤ 3,0 mg/kg

	Cadmium: $\leq 1,0$ mg/kg Mercury: $\leq 0,1$ mg/kg Microbiological criteria: Total aerobic microbial count: $\leq 5 \times 10^3$ CFU/g Total yeast and mould count: $\leq 10^2$ CFU/g Viable <i>Yarrowia lipolytica</i> cells ⁽²⁾: < 10 CFU/g (i.e. limit of detection) Coliforms: ≤ 10 CFU/g <i>Salmonella</i> spp.: Absence in 25 g CFU: colony forming units
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⁽¹⁾ Expressed as selenium.

⁽²⁾ Applicable at all stages after the heat-treatment step to guarantee the absence of viable *Yarrowia lipolytica* cells and to be first tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable *Yarrowia lipolytica* cells during packaging and/or storage of the novel food.'

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/1994
of 4 December 2020**

correcting Implementing Regulation (EU) 2020/1156 extending the definitive anti-dumping duty imposed by Implementing Regulation (EU) 2018/186 on imports of certain corrosion resistant steels originating in the People's Republic of China to imports of slightly modified certain corrosion resistant steels

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾, and in particular Articles 13(3), 14(1) and 14(5) thereof,

Whereas:

- (1) By Commission Implementing Regulation (EU) 2020/1156 ⁽²⁾, the Commission extended the anti-dumping measures on certain corrosion resistant steels originating in the People's Republic of China to certain slightly modified corrosion resistant steels originating in the People's Republic of China.
- (2) In particular, the Commission concluded that the definitive anti-dumping duties imposed on the product concerned as defined in the original investigation were circumvented by imports of the slightly modified product originating in the People's Republic of China. The investigation showed that there was a change in the pattern of trade between the People's Republic of China and the Union which stemmed from a practice, process or work for which there was insufficient due cause or economic justification other than the imposition of the duty. The Commission also found that the remedial effects of the duties were being undermined in terms of the prices and/or quantities of the like product. Finally, the Commission found dumping for the slightly modified product in relation to the normal values previously established. Therefore, in accordance with Article 13(1) of Regulation (EU) 2016/1036 ('the basic Regulation'), the Commission concluded that the anti-dumping measures in force on imports of certain corrosion resistant steels originating in the People's Republic of China should be extended to imports of the slightly modified product originating in the People's Republic of China.
- (3) Accordingly, Article 1(1) of this Regulation stated that the definitive anti-dumping duty imposed by Commission Implementing Regulation (EU) 2018/186 ⁽³⁾ was extended to the slightly modified product. However, such provision omitted an explicit reference to the applicable level of duties.
- (4) For the sake of clarity, and in accordance with Article 13(1), second paragraph of the basic Regulation, the extended duty is the one applicable to 'all other companies' in the original measures. Article 13(1) of the basic Regulation was already referred to as the basis to extend the measures in recital 64 of Implementing Regulation (EU) 2020/1156. According to Article 13(1), second paragraph of the basic Regulation, the Commission may extend the duties up to the residual anti-dumping duty imposed for the country subject to measures. Therefore, the reference to this provision as well as the findings made in the anti-circumvention investigation on the basis of facts available clearly indicate that the extended duty should be the one established in Article 1(2) of Implementing Regulation (EU) 2018/186 for 'all other companies', which is a definitive anti-dumping duty of 27,9 %.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Commission Implementing Regulation (EU) 2020/1156 of 4 August 2020 extending the definitive anti-dumping duty imposed by Implementing Regulation (EU) 2018/186 on imports of certain corrosion resistant steels originating in the People's Republic of China to imports of slightly modified certain corrosion resistant steels (OJ L 255, 5.8.2020, p. 36).

⁽³⁾ Commission Implementing Regulation (EU) 2018/186 of 7 February 2018 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of certain corrosion resistant steels originating in the People's Republic of China (OJ L 34, 8.2.2018, p. 16).

- (5) Furthermore, Article 1(1) of Implementing Regulation (EU) 2020/1156 included some typographical errors, resulting in an unclear description of the product and CN codes covered by the extended anti-dumping duty, which needed to be corrected. The scope of the product under investigation (compared to the product concerned by Implementing Regulation (EU) 2018/186) was clearly defined in recitals 10 and 11 of Implementing Regulation (EU) 2020/1156.
- (6) Therefore, the Commission has decided to correct recital 64 and Article 1(1) of Implementing Regulation (EU) 2020/1156 in order to confirm the applicable level of anti-dumping duties. As set out in recital 65 and Article 1(4) of Implementing Regulation (EU) 2020/1156, the correct level of anti-dumping duty as clarified in the previous recital should also be collected on the imports of the product under investigation originating in the People's Republic of China which entered the Union under registration imposed by the initiating Commission Implementing Regulation (EU) 2019/1948 ⁽⁴⁾. Therefore, the effects of this correction should start from the entry into force of Implementing Regulation (EU) 2020/1156 (namely, 6 August 2020) and includes the collection of the duties on the imports of the product under investigation subject to registration.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee, established by Article 15(1) of Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

1. Recital 64 of Implementing Regulation (EU) 2020/1156 is replaced by the following:

‘(64) In accordance with Article 13(1) of the basic Regulation, the anti-dumping measures in force on imports of certain corrosion resistant steels originating in the PRC should therefore be extended to imports of the product under investigation originating in the PRC. Pursuant to Article 13(1), second paragraph of the basic Regulation, the measure to be extended should be the one established in Article 1(2) of Implementing Regulation (EU) 2018/186 for “all other companies”, which is a definitive anti-dumping duty of 27,9 % applicable to the net, free-at-Union-frontier price, before duty.’

2. Article 1(1) of Implementing Regulation (EU) 2020/1156 is replaced by the following:

‘1. The definitive anti-dumping duty applicable to “all other companies” imposed by Article 1(2) of Implementing Regulation (EU) 2018/186 on imports of certain corrosion resistant steels originating in the People's Republic of China is hereby extended to imports of flat-rolled products of iron or alloy steel or non-alloy steel; plated or coated by hot dip galvanisation with zinc and/or aluminium and/or magnesium, whether or not alloyed with silicon; chemically passivated; with or without any additional surface treatment such as oiling or sealing; containing by weight: not more than 0,5 % of carbon, not more than 1,1 % of aluminium, not more than 0,12 % of niobium, not more than 0,17 % of titanium and not more than 0,15 % of vanadium; presented in coils, cut-to-length sheets and narrow strips, currently falling under CN codes ex 7210 41 00, ex 7210 49 00, ex 7210 61 00, ex 7210 69 00, ex 7210 90 80, ex 7212 30 00, ex 7212 50 61, ex 7212 50 69, ex 7212 50 90, ex 7225 92 00, ex 7225 99 00, ex 7226 99 30, ex 7226 99 70 (TARIC codes: 7210 41 00 30, 7210 49 00 30, 7210 61 00 30, 7210 69 00 30, 7210 90 80 92, 7212 30 00 30, 7212 50 61 30, 7212 50 69 30, 7212 50 90 14, 7212 50 90 92, 7225 92 00 30, 7225 99 00 23, 7225 99 00 41, 7225 99 00 93, 7226 99 30 30, 7226 99 70 13, 7226 99 70 93), originating in the People's Republic of China.

The following products are excluded:

- of stainless steel, of silicon-electrical steel, and of high-speed steel,
- not further worked than hot-rolled or cold-rolled (cold-reduced),
- the product as defined in Article 1(1) of Implementing Regulation (EU) 2018/186.’

Article 2

This Regulation shall enter into force with retroactive effect as from 6 August 2020.

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/1948 of 25 November 2019 initiating an investigation concerning possible circumvention of anti-dumping measures imposed by Commission Implementing Regulation (EU) 2018/186 on imports of certain corrosion resistant steels originating in the People's Republic of China, and making such imports subject to registration (OJ L 304, 26.11.2019, p. 10).

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

Done at Brussels, 4 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1995**of 4 December 2020****amending Implementing Regulation (EU) No 2018/1261 as regards administrative changes of the information related to the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 50(2) thereof,

Whereas:

- (1) On 20 September 2018, a Union authorisation with authorisation number EU-0018397-0000 was granted by Commission Implementing Regulation (EU) 2018/1261 ⁽²⁾ to HYPRED SAS for the making available on the market and use of the biocidal product family ‘Hypred’s iodine based products’.
- (2) On 04 April 2019, HYPRED SAS submitted a notification to the European Chemicals Agency (‘the Agency’), in accordance with Article 11(1) of Commission Implementing Regulation (EU) No 354/2013 ⁽³⁾, in respect of administrative changes to the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’ as described in Title 1, Sections 1 and 2 of the Annex to that Regulation.
- (3) HYPRED SAS proposed the following changes to the summary of the product characteristics for the biocidal product family ‘Hypred’s iodine based products’, as set out in the Annex to Implementing Regulation (EU) 2018/1261: (a) the addition of names for the biocidal product family in Section 7.1 of the third information level: individual products in the meta SPCs 1, 2, 3 and 5; (b) the change of the name of the authorisation holder in Section 1.3; (c) the addition of two manufacturers for the active substance and their respective manufacturing sites in Section 1.5; (d) the change of administrative details of the manufacturer in Section 1.4; (e) changes of administrative details of the location of existing manufacturing sites, and addition of location of new manufacturing sites in Section 1.4. The notification was recorded under case number BC-KC049719-36 in the Register for Biocidal Products.
- (4) On 19 June 2019, the Agency submitted to the Commission an opinion on the proposed changes, in accordance with Article 11(3) of Implementing Regulation (EU) No 354/2013. The opinion concludes that the amendments to the existing authorisation sought by the authorisation holder falls under the category of change set out in Article 50(3)(a) of Regulation (EU) No 528/2012, and that after the implementation of the changes the conditions of Article 19 to that Regulation are still met.
- (5) On 28 June 2019, the Agency transmitted to the Commission the revised summary of the biocidal product characteristics in all the official languages of the Union in accordance with Article 11(6) of Implementing Regulation (EU) No 354/2013.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to amend the Union authorisation of the biocidal product family ‘Hypred’s iodine based products’.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2018/1261 of 20 September 2018 granting a Union authorisation for the biocidal product family Hypred’s iodine based products (OJ L 238, 21.9.2018, p. 33).

⁽³⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2018/1261 is amended as follows:

- (1) in Article 1, 'HYPRED SAS' is replaced by 'HYPRED SAS – KERSIA Group';
- (2) the Annex is replaced by the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 4 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's iodine based products

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018397-0000

R4BP asset number: EU-0018397-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	HYPRED's iodine based products

1.2. **Product type(s)**

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

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	HYPRED SAS – KERSIA Group
	Address	55, Boulevard Jules Verger - BP10180 35803 DINARD Cedex France
Authorisation number	EU-0018397-0000	
R4BP asset number	EU-0018397-0000	
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	HYPRED SAS – KERSIA Group
Address of manufacturer	55, Boulevard Jules Verger - BP10180 35803 DINARD France
Location of manufacturing sites	HYPRED SAS – KERSIA Group - 55, Boulevard Jules Verger - BP10180 35803 DINARD France KERSIA POLSKA Sp.z.o.o. - NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland KERSIA IBERICA SL - Pol. Miguel Eguía C/Zarapuz s/n 31200 ESTELLA (NAVARRA) Spain KERSIA DEUTSCHLAND GmbH Marie-Curie-Straße 23 53332 Bornheim – Sechtem Germany

	HYPRED Italia s.r.l. – KERSIA Group Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy AG France S.A.S – KERSIA Group - Zone Industrielle Le Roineau, 72500 VAAS, FRANCE KERSIA DEUTSCHLAND GmbH - OBERBRÜHLSTRAßE 16-18, 87700 MEMMINGEN, GERMANY KERSIA AUSTRIA GmbH - PFONGAUERSTRAßE 17, 5202 NEUMARKT AM WALLERSEE, AUSTRIA Kilco Holdings Ltd – KERSIA Group - Broomhouses 2 Industrial Estate, Old Glasgow Road, LOCKERBIE - DG11 2SD, UNITED KINGDOM Kilco (International) Ltd – KERSIA Group - 1A Trench Road Mallusk, Newtownabbey, CO ANTRIM BT36 4TY, IRELAND Medentech Ltd – KERSIA Group - Clonard Road, WEXFORD, Y35Y7WY, IRELAND
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1.5. Manufacturer(s) of the active substance(s)

Active substance	Iodine
Name of manufacturer	COSAYACH : SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5
Address of manufacturer	Terrenos de Elena S/N Terrenos de Elena S/N Huara, Región de Tarapacá Chile
Location of manufacturing sites	Mined at: S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad. Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF MINERA SA
Address of manufacturer	San Martín 499 Iquique Chile
Location of manufacturing sites	Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SOCIEDAD QUIMICA y MINERA SA
Address of manufacturer	Los Militares 4290 SANTIAGO DE CHILE Chile
Location of manufacturing sites	Pedro de Valdivia (PV) Route B 180 Antofagasta Chile Nueva Victoria (NV) Route 5 North, Km 1925 Pozo Almonte Chile

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

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd
Address of manufacturer	661 Mobara 297-8550 Mobara City, Chiba Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami Hinata, 299-4205 Shirako-Machi, Chosei-Gun, 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
Iodine		Active substance	7553-56-2	231-442-4	0,25	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	24,199

2.2. Type(s) of formulation

Formulation(s)	AL - Any other liquid SL - Soluble concentrate

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 : Dipping products - ready to use
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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)

2. META SPC 1 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	4,993

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	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. **Use description****Table 1. Use # 1 – Manual or automated dipping after milking**

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 ml recommended) — sheep (1.5 to 5 ml : 1.5 ml recommended) — goats (2.5 to 6 ml : 2.5 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

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*

None: 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.

The product must be brought to a temperature above 20°C before use.

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

Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

— cows and buffaloes (3 to 10ml : 5 ml recommended)

⁽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.

— sheep (1.5 to 5 ml : 1.5 ml recommended)

— goats (2.5 to 6 ml : 2.5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes :

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	Dip-io 2500 JOD DIP IODERM PSP DERMINO FR Iododip IODEX EXTRA Iodystrong DERMIODE INO IODE EPAIS INO STAR + IODACTIV 2500 IODIUM BX2500 Usual Iod Post ASiRAL Dip Coat IODOCAN EXTRA UDDER PLUS PRIMADIODE CERTIODE EPAIS IODIPACK GEL HELIO IODE EPAIS VAGEL GELAPIS ACTIV IOSAPIS GEL ZENCARE FLASH REPROGEL DERMADINE + KRONI Jod Dipp 2500 WÜBBELMANN JOD DIP Iodine Cleaner&Sanitizer MUNGIFILM ZEP FS FILMIODINE NIPPLE NP IODOFILM EMPRASAN UDDER SHIELD ANGLIA FARMERS IO-FILM BARRICADE STANTON IODOFILM WYNN SAN IOFILM TEAT DIP				
Authorisation number	EU-0018397-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697

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

Trade name(s)	Dip-io YB MAX INO Io Dip MAX JOD DIP YB MAX IodoDip YB MAX
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	Iodium Dip YB MAX JodyDip YB MAX Delta IoDip YB MAX				
Authorisation number	EU-0018397-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	meta SPC 2 : Dipping, foaming, spraying products - Ready to use
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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)

2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	4,69

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	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

Table 2. Use # 1 – Manual or automated dipping, foaming or spraying before milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming or spraying before milking - Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1.5 to 5 ml : 1.5 to 3ml recommended) — goats (2.5 to 6 ml : 2.5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

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.

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

4.2. **Use description**

Table 3. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying after milking - Manual or automated disinfection of teats by dipping, foaming or spraying after milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended)

	— goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. *Use-specific instructions for use*

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

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.

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 2

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 2

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 2

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

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 product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

Where necessary repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

- In the event of inhalation: Bring to fresh air.
- In the event of contact with the skin: Wash with water.
- In the event of contact with the eyes :

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

6. OTHER INFORMATION

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)	Liq-io 2500 JOD SPRAY IODINE 3000 RTU IODEX 2500 Usual Iod Liquid Iodoliquid Iodospray DESINTEAT IODYSPRAY RBT 2500 IODY'FLASH INO IODE SPRAY IODYPRO 2500 IODYPRO BL2500 Robot Liq-io 25 ADF iDip+ ASiRAL Dip Spray J IODIPACK
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	HELIO IODE LIQUIDE POLY-IODE CERTIODE LIQUIDE IOSAPIS FLUID GELAPIS ROBOT ZENCARE SPRAY HELIO IODE SPRAY + IODIP + KRONI Jod Spray 2500 WÜBBELMANN JOD LIQUID PRECEPT ANGLIA FARMERS PRECLENZ H&M PREDIP FULLWOOD PRECLEANSE M WILLIAMS PRECEPT STANTON PREDIP RTU WYNN SAN IODINE PREDIP RTU PREMIER GOLD PRE-DIP HODGES & MOSS PREDIP LANODIP PREPOST DAIRYSAN MULTICARE EMPRASAN ADVANCE UDDERWASH IODINE ANGLIA FARMERS PREPOST-IO PREMIER GOLD PRE/POST FULLWOOD PRE/POST IODINE HODGES & MOSS ADVANCE WYNN SAN IODINE PREPOST				
Authorisation number	EU-0018397-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697

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

Trade name(s)	Liq-io YB MAX INO Io Liquid Max Iodoliquid YB MAX Iodospray YB MAX Desinteat YB MAX Iodium Spray YB MAX JodySpray YB MAX Delta IoSpray YB MAX				
Authorisation number	EU-0018397-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49

Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69
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META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3 : Dipping, foaming, spraying concentrated products
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1.2. **Suffix to the authorisation number**

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
Iodine		Active substance	7553-56-2	231-442-4	2,5	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		24,1-99	24,199

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

Formulation	SL - Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Causes serious eye damage. May cause damage to organs (thyroid) through prolonged or repeated exposure oral. Toxic to aquatic life with long lasting effects. May be corrosive to metals.
Precautionary statements	Keep out of reach of children. Do not breathe mist. Do not breathe vapours. Do not breathe spray. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center / doctor. Get medical advice/attention if you feel unwell. Dispose of contents to in accordance with local/ regional/ national/ international regulations. Dispose of container to in accordance with local/ regional/ national/ international regulations. Keep only in original container. Absorb spillage to prevent material damage.

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

4.1. Use description

Table 4. Use # 1 – Manual or automated dipping, foaming or spraying before milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	A dilution at 10% (v/v) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1.5 to 5 ml: 1.5 to 3 ml recommended) — goats (2.5 to 6 ml: 2.5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional

Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L
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4.1.1. *Use-specific instructions for use*

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal and yeasticidal activity.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

4.1.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

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.

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 5. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying -

	Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10% (v/v: 10 ml product, add water up to 100ml) should be prepared. For disinfection of viruses a dilution at 20% (v/v: 20 ml product, add water up to 100ml) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. Use-specific instructions for use

Prepare a dilution at 10% (v/v: 10 ml product, add water up to 100ml) for bactericidal, yeasticidal and algacidal activity or 20% (v/v: 20 ml product, add water up to 100ml) in case virucidal activity is also needed.

Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3

4.2.2. Use-specific risk mitigation measures

For manual spraying applications wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) /protective clothing/eye protection.

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.

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 ^(*) 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 product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping / foaming cup / sprayer manually or automatically with the prepared dilution.

Where necessary, repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

In case of faintness, get medical advice/attention. Show this safety data sheet to the doctor.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.

Remove contact lenses if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or doctor/physician.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

6. OTHER INFORMATION

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

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)	Liq-io concentrate INO Jod Konzentrat Usual Iod Concent Iodoconcentrat D 10 IODINE D 5 IODINE Liq-io C INO IODE C D 4 IODINE ADF iDip+ concentrate Mammizan Concentré WYNNSAN IODINE CONCENTRATE EMPRASAN OPTIMA ANGLIA FARMERS CONC PROLAC SENTINEL CONC PREMIER GOLD CONCENTRATE FULLWOOD IODINE CONC H&M OPTIMA SENTINAL CONC HARRY TRAVIS SUPER CONC TEAT DIP LANODIP CONC E/SAN SOVEREIGN PROLAC SENTINEL CONC				
Authorisation number	EU-0018397-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		24,199

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	meta SPC 4 : Dipping products reaching virucidal activity – Ready to use
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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)
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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 (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,5	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993	4,993

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	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

Table 6. Use # 1 – Manual or automated dipping after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 ml recommended) — sheep (1,5 to 5 ml : 1,5 ml recommended) — goats (2,5 to 6 ml : 2,5 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

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 (*) 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 product must be brought to a temperature above 20°C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

— cows and buffaloes (3 to 10ml : 5 ml recommended)

— sheep (1,5 to 5 ml : 1,5 ml recommended)

— goats (2,5 to 6 ml : 2,5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. Risk mitigation measures

Wear eye protection.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes :

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

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)	Dip-io 5000 IODIUM TX INO JOD 50 DIP Usual Iod Post + IODIUM PRO DIP IODERM PSP + IODEX EXTRA + Iododip + IODYSTRONG PLUS INO TREMP INO STAR IODACTIV 5000 DERMINO IODERM 5000 IODIUM BX5000 HOEVE-PLUS DIP TREMPASEPT IODE DERMADINE MAMMO-DERM KRONI Jod Dipp 5000				
Authorisation number	EU-0018397-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta SPC 5 : Dipping, foaming, spraying products 5500 ppm – Ready to use
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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
Iodine		Active substance	7553-56-2	231-442-4	0,55	0,55
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14- (even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69	4,69

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

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

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

4.1. Use description

Table 7. Use # 1 – Manual or automated dipping, foaming or spraying before milking

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

Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.1.1. *Use-specific instructions for use*

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC5.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application : Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/ eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing /eye protection.

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.

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

4.2. Use description

Table 8. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10ml : 5 to 8 ml recommended) — sheep (1,5 to 5 ml : 1,5 to 3ml recommended) — goats (2,5 to 6 ml : 2,5 to 4 ml recommended) Frequency : 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1000L

4.2.1. Use-specific instructions for use

Fill the dipping / foaming cup / sprayer manually or automatically with the ready to use product.

Manual or automatic dipping / foaming / spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried. (at least 5 minutes)

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 5.

4.2.2. Use-specific risk mitigation measures

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

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.

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 5

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 5

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 5

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

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 product must be brought to a temperature above 20°C before use.

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

Where necessary repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

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

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes :

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

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.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

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

Shelf life : 2 years in HDPE

Do not store at a temperature higher than 30°C.

6. OTHER INFORMATION

^(*) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

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)	Liq-io 5500 IODYPRO INO JOD 50 Liquid Usual Iod Liquid + IODIUM PRO SPRAY IODEX Iodoliquid + Iodospray Plus DESINTEAT PLUS ROBOSPRAY IODE INOTRAYON IODYPRO 5500 Robot Liq-io 55 IODYPRO BL5500 ADF iDip+ 5500 HOEVE-JODIUM SPRAY GRUPAIODE IODOCAN JOFO JODI PLUS K-AGRO PRODIP ID IODIP HELIO IODE SPRAY MAMMO-JOD KRONI Jod Spray 5500 MUNGI-IOD LELY QUARESS-Iodine GOLD GLYCODIP EMPRASAN EXTRA CARE H&M RTU IODINE ANGLIA FARMERS SUPPLEDIP-IO PROLAC RTU IODINE TEAT DIP PREMIER GOLD POST DIP FULLWOOD IODINE EXTRA H&M EXTRACARE M WILLIAMS TEAT DIP PLATINUM WDH GOLD DIP RTU WYNNSAN IODINE HE RTU				
Authorisation number	EU-0018397-0007 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,55
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/1996

of 4 December 2020

amending the Annex to Implementing Decision (EU) 2020/1742 concerning certain protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in the United Kingdom

(notified under document C(2020) 8763)

(Only the English text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community ('Withdrawal Agreement'),

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof, in conjunction with Article 131 of the Withdrawal Agreement,

Whereas:

- (1) Commission Implementing Decision (EU) 2020/1742 ⁽³⁾ was adopted following outbreaks of highly pathogenic avian influenza (HPAI) of subtype H5N8 in holdings where poultry or other captive birds are kept in the United Kingdom, and the establishment of protection and surveillance zones by the competent authority of the United Kingdom in accordance with Council Directive 2005/94/EC ⁽⁴⁾.
- (2) Implementing Decision (EU) 2020/1742 provides that the protection and surveillance zones established by the United Kingdom in accordance with Directive 2005/94/EC are to comprise at least the areas listed as protection and surveillance zones in the Annex to that Implementing Decision.
- (3) Since the date of adoption of Implementing Decision (EU) 2020/1742, the United Kingdom has notified the Commission of new outbreaks of HPAI of subtype H5N8 in holdings where poultry or other captive birds are kept in Leicestershire and North Yorkshire, and it has taken the necessary measures required in accordance with Directive 2005/94/EC, including the establishment of protection and surveillance zones around these new outbreaks.
- (4) The Commission has examined those measures in collaboration with the United Kingdom, and it is satisfied that the borders of the protection and surveillance zones, established by the competent authority of the United Kingdom, are at a sufficient distance to the holdings where the new outbreaks of HPAI of subtype H5N8 have been confirmed.

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ Commission Implementing Decision (EU) 2020/1742 of 20 November 2020 concerning certain protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in the United Kingdom (OJ L 392, 23.11.2020, p. 60).

⁽⁴⁾ Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

- (5) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe at Union level, in collaboration with the United Kingdom the new protection and surveillance zones established by the United Kingdom in accordance with Directive 2005/94/EC. Therefore, the protection and surveillance zones listed for the United Kingdom in the Annex to Implementing Decision (EU) 2020/1742 should be amended.
- (6) Accordingly, the Annex to Implementing Decision (EU) 2020/1742 should be amended to update regionalisation at Union level to take account of the new protection and surveillance zones established in accordance with Directive 2005/94/EC by the United Kingdom and the duration of the restrictions applicable therein.
- (7) Implementing Decision (EU) 2020/1742 should therefore be amended accordingly.
- (8) Given the urgency of the epidemiological situation in the Union as regards the spread of HPAI of subtype H5N8, it is important that the amendments to be made to the Annex to Implementing Decision (EU) 2020/1742 by this Decision take effect as soon as possible.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2020/1742 is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 4 December 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

‘ANNEX

PART A

Protection zone as referred to in Article 1:

United Kingdom

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Those parts of Cheshire County (ADNS code 00140) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	27.11.2020
Those parts of Herefordshire County (ADNS code 00051) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	8.12.2020
Those parts of Leicestershire County (ADNS code 00152) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.78 and W0.86	16.12.2020
Those parts of North Yorkshire County (ADNS code 00176) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N54.30 and W1.47	23.12.2020

PART B

Surveillance zone as referred to in Article 1:

United Kingdom

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Those parts of Cheshire County (ADNS code 00140) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	6.12.2020
Those parts of Cheshire County (ADNS code 00140) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N53.25 and W2.81	From 28.11.2020 until 6.12.2020
Those parts of Herefordshire County (ADNS code 00051) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	17.12.2020
Those parts of Herefordshire County (ADNS code 00051) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.17 and W2.81	From 9.12.2020 until 17.12.2020
Those parts of Leicestershire County (ADNS code 00152) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N52.78 and W0.86	25.12.2020
Those parts of Leicestershire County (ADNS code 00152) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N52.78 and W0.86	From 17.12.2020 until 25.12.2020

Those parts of North Yorkshire County (ADNS code 00176) extending beyond the area described in the protection zone and within the circle of a radius of ten kilometres, centred on WGS84 dec. coordinates N54.30 and W1.47	31.12.2020
Those parts of North Yorkshire County (ADNS code 00176) contained within a circle of a radius of three kilometres, centred on WGS84 dec. coordinates N54.30 and W1.47	From 24.12.2020 until 31.12.2020'

DECISION (EU) 2020/1997 OF THE EUROPEAN CENTRAL BANK
of 24 November 2020
on the approval of the volume of coin issuance in 2021 (ECB/2020/57)

THE EXECUTIVE BOARD OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 128(2) thereof,

Having regard to Decision (EU) 2015/2332 of the European Central Bank of 4 December 2015 on the procedural framework for the approval of the volume of euro coin issuance (ECB/2015/43) ⁽¹⁾, and in particular Article 2(9) thereof,

Whereas:

- (1) The European Central Bank (ECB) has the exclusive right since 1 January 1999 to approve the volume of coins issued by the Member States whose currency is the euro (hereinafter 'euro area Member States').
- (2) The 19 euro area Member States have submitted to the ECB their requests for the approval of the volume of coins to be issued in 2021, supplemented by explanatory notes on the forecasting methodology. Certain of these euro area Member States have also provided additional information regarding circulation coins, where such information is available and considered important by the euro area Member States concerned to substantiate the approval request.
- (3) As the right of euro area Member States to issue euro coins is subject to approval by the ECB of the volume of the issue, in accordance with Article 3 of Decision (EU) 2015/2332 (ECB/2015/43), the volumes approved by the ECB may not be exceeded by the euro area Member States without prior approval by the ECB.
- (4) Pursuant to Article 2(9) of Decision (EU) 2015/2332 (ECB/2015/43), as no modification of the requested volume of coin issuance is required, the Executive Board is empowered to adopt this decision on the approval requests for the volume of coin issuance in 2021 submitted by euro area Member States,

HAS ADOPTED THIS DECISION:

Article 1

Definitions

For the purposes of this Decision, the following definitions apply:

- (a) 'volume of coin issuance' means volume of coin issuance as defined in point 3 of Article 1 of Decision (EU) 2015/2332 (ECB/2015/43);
- (b) 'circulation coins' means circulation coins as defined in point 1 of Article 2 of Council Regulation (EU) No 729/2014 ⁽²⁾;
- (c) 'collector coins' means collector coins as defined in point 3 of Article 1 of Regulation (EU) No 651/2012 of the European Parliament and of the Council ⁽³⁾.

⁽¹⁾ OJ L 328, 12.12.2015, p. 123.

⁽²⁾ Council Regulation (EU) No 729/2014 of 24 June 2014 on denominations and technical specifications of euro coins intended for circulation (OJ L 194, 2.7.2014, p. 1).

⁽³⁾ Regulation (EU) No 651/2012 of the European Parliament and of the Council of 4 July 2012 on the issuance of euro coins (OJ L 201, 27.7.2012, p. 135).

Article 2

Approval of the volume of euro coins to be issued in 2021

The ECB hereby approves the volume of euro coins to be issued by the euro area Member States in 2021 as set out in the following table:

(million EUR)

	Volume of euro coins approved for issuance in 2021		
	Circulation coins	Collector coins (not intended for circulation)	Volume of coin issuance
Belgium	33,0	1,0	34,0
Germany	417,0	241,0	658,0
Estonia	10,4	0,3	10,7
Ireland	15,8	0,5	16,3
Greece	99,5	3,6	103,1
Spain	291,5	30,0	321,5
France	243,0	50,0	293,0
Italy	169,3	2,7	172,0
Cyprus	11,0	0,1	11,1
Latvia	5,5	0,2	5,7
Lithuania	20,0	0,6	20,6
Luxembourg	14,7	0,4	15,1
Malta	8,2	0,3	8,5
Netherlands	0,0	0,1	0,1
Austria	62,5	153,5	216,0
Portugal	31,5	2,0	33,5
Slovenia	21,0	1,0	22,0
Slovakia	14,0	2,0	16,0
Finland	15,0	10,0	25,0
Total	1 482,9	499,3	1 982,2

Article 3

Taking effect

This Decision shall take effect on the day of its notification to the addressees.

Article 4

Addressees

This Decision is addressed to the euro area Member States.

Done at Frankfurt am Main, 24 November 2020.

The President of the ECB
Christine LAGARDE

CORRIGENDA

Corrigendum to Council Decision (EU) 2020/1532 of 12 October 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification Opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 406 of 3 December 2020)

This corrigendum should be considered null and void.

Corrigendum to Council Decision (EU) 2020/1532 of 12 October 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification Opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 352 of 22 October 2020)

The Annex should read:

‘ANNEX

This Annex supplements the Annex to Decision (EU) 2020/1410.

II.2. Development of correlation tables between the 2017 and 2022 versions of the Harmonized System (Doc. NC2704, NC2749 and NC2753)

Concerning the correlation table for subheadings 4407.13 and 4407.14 (mixtures of S-P-F (spruce, pine and fir) and Hem-fir (Western hemlock and fir)), the Union shall support the correlations proposed by the WCO Secretariat in paragraph 20 of document NC2753.

Concerning the correlation table for subheading 4418.83 (I beams), the Union shall support the correlations proposed by Japan in paragraph 14 of document NC2753.

Concerning the correlation table for subheading 7019.71 (veils/thin sheets of glass fibres), the Union notes that the only transfer from HS 2017 would be from subheading 7019.32.

Concerning the correlation table for subheadings 8462.62 and 8462.63 (forging machines), the Union shall support keeping all the subheadings proposed for transfer mentioned under HS 2017, including the ones in square brackets.

Concerning the correlation table for subheading 8519.81 (telephone answering machines), the Union shall support the proposal of the WCO Secretariat in paragraph 26 of document NC2704.

Concerning the correlation table for subheading 8539.51 (LED), the Union shall support the WCO Secretariat's conclusion in paragraph 24 of document NC2704.

Concerning the correlation table for new subheading 8541.51 (semiconductor-based transducers), the Union notes that there is no evidence of parts classified separately in the HS 2017 version. Therefore no additional transfers are needed.

Concerning the correlation table for heading 88.06 (unmanned aircraft), the Union shall support option (i) mentioned in paragraph 25 of document NC2704.

Finally, the Union shall support the correction of some editorial errors in the draft Correlation Tables I and II, as set out in the Annex to document NC2753.

III.4. Classification in HS 2022 of certain collections and collectors' pieces of numismatic interest (Request by the Secretariat) (Doc. NC2711, NC2754)

The Union would classify the three products in the new subheading 9705.31 in HS 2022. The Union notes that both Canada and the WCO Secretariat support the Union's proposal to delete the mention of the "coins generally known in the trade as 'ancients' or 'ancient coins'" from the second paragraph of Item (4) of new Part (A) of HSEs to heading 97.05.

III.5. Classification in HS 2022 of cartridges for 3D printers (Request by the Secretariat) (Doc. NC2712, NC2755)

The Union shall support the proposal for amending the HSEs which specifies that 3D printer cartridges with electronic components or mechanical mechanisms should be classified as parts of 3D printers.

The Union would classify products presented in both documents NC2712 and NC2755 in heading 84.85 in HS 2022 as parts of 3D printers considering the presence of electronic components for connection to a 3D printer.

III.7. Report of the 57th Session of the HS Review Sub-Committee (Doc. NR1434)

III.8. Matters for decision (Doc. NC2709)

- (a) Annexes C/4 and D/8 – Amendments to the Explanatory Notes (HS 2022) (Section VI)
- (b) Annexes C/5, D/9 and D/22 – Amendments to the Explanatory Notes (HS 2022) (Section VII)
- (c) Annexes C/8 and D/12 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Section XIII)
- (d) Annexes C/13 and D/17 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Section XX)
- (e) Annexes C/14 and D/18 – Possible amendments to the Explanatory Notes in respect of certain amusement park equipment (Proposal by the United States)

The Union shall agree to all proposed amendments in those documents.

- (f) Annexes C/1 and D/5 – Possible amendments to the Explanatory Notes to heading 15.09 in respect of other virgin olive oils, and heading 15.15 in respect of examples of microbial fats and oils

Concerning the HSEs to heading 15.09, the Union shall support the Union's proposal (option 2) and the new Canadian proposal (option 3). In item (D)(2), the Union shall support the use of "or" (option 2) instead of "and/or".

Concerning the HSEs to heading 15.15, the Union shall support the use of the expression "single cell organism" (option 1), and the use of "or" (option 2) instead of "and/or". In examples (a) and (b), the Union shall support the use of the expression "obtained from" (option 2).

- (g) Annexes C/3 and D/7 – Possible amendments to the Explanatory Notes in respect of "placebos" and "double-blinded clinical trial kits" in heading 30.06 (Request by Australia)

Concerning the sentence "The placebos of this heading also include [control vaccines] [controlled vaccines] [vaccines which are used as control substances and] that have been licensed for use in recognized clinical trials.", the Union shall not support adding this sentence to the text of item (12) of the HSEs to heading 30.06, as it is not clear what kind of substances are described by it. If the other Contracting Parties decide to add it, the Union shall support "vaccines which are used as control substances" (option 3), or if flexibility is needed, "control vaccines" (option 1).

Concerning the sentence "[Active ingredients to be trialled can include herbal medicinal products [for therapeutic or prophylactic uses].]", the Union shall remain flexible for adding it to the text, but shall not support an open list of examples as suggested by the United States.

- (h) Annexes C/6 and D/10 – Amendments to the Explanatory Notes Consequential to the Article 16 Recommendation of 28 June 2019 (Section IX)

The Union shall support the proposal to add Subheading Explanatory Notes to subheadings 4412.41, 4412.42 and 4412.49. The Union shall request that the proposed text needs to be further analysed and improved in order to bring it in line with the current classification practices in the Union (for example, the orientation of the veneers).

- (i) Annexes C/7 and D/11 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Sections XI and XII)

The Union shall support adding "paraseismic wall covering" and "geotextiles" to the list of examples of electronic textiles. In the text on "geotextiles", the Union shall support the text "a sensor made of fibres or at least being fully integrated in the fibres" (option 2) as previously suggested by the Union.

The Union shall support provisionally adopting the texts approved by the HS Review Sub-Committee.

- (j) Annexes C/12 and D/16 – Amendments to the Explanatory Notes Consequential to the Article 16 Recommendation of 28 June 2019 (Section XVII)

The Union shall support adding the reference to permanently integrated cameras in paragraph 3 of the HSEs to heading 88.06, provided that the Classification Opinion classifying a drone with an integrated camera in heading 85.25 is reviewed and aligned with HS 2022 and HSEN.

In relation to paragraph 4 of the HSEs to heading 88.06, the Union shall support the proposal by China with additional technical criteria introduced by the Union (second option).

- (k) Annexes C/15 and D/19 – Possible amendment to the Explanatory Notes to Chapter 97 in respect of certain cultural articles (Proposal by the United States)

The Union shall not support the list of items mentioned as examples, as these are very specific and limited to explain the scope of the articles to be classified under subheading 9705.10.

The Union further notes that the definitions and examples provided would not give clarity on how to classify for example “traditional national costumes” or “old cars”.

- (l) Annexes C/16 and D/20 – Amendment to the GIR’s Explanatory Notes (HS 2022)

The Union shall support the original proposal by the WCO Secretariat (option 1, using the term “merely”, but remaining flexible for the expression “not further worked than”) and shall request to align the texts in English and French.

- III.9. Possible amendment of the Explanatory Note to heading 71.04 in relation to synthetic diamonds (Proposal by the Kimberley Process) (Doc. NC2757)

The Union shall agree to the proposed modifications to the new third paragraph to heading 71.04 and to the creation of new item (3) of the subheading Explanatory Notes to subheading 7104.91.

- III.10. Classification of a micro-electro-mechanical systems (MEMS) element in HS 2022 (Proposal by the Secretariat)

The Union would classify the product in heading 85.41.’

Corrigendum to Council Decision (EU) 2020/1410 of 25 September 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 406 of 3 December 2020)

This corrigendum should be considered null and void.

Corrigendum to Council Decision (EU) 2020/1410 of 25 September 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 327 of 8 October 2020)

The Annex should read:

‘ANNEX

IV. REPORT OF THE SCIENTIFIC SUB-COMMITTEE: Doc. NS0456Eb (SSC/35 - report)

(1) Matters for decision (doc. NC2708Ea)

- (a) Annexes A/1 and C/1 – Classification of new INN products (List 120). The Union shall approve the 125 classifications (HS 2017 Edition) and the three consequential reclassifications (HS 2022 Edition) recommended by the Scientific Sub-Committee.
- (b) Annexes A/2 and C/2 – Classification of new INN products (List 121). The Union shall approve the 143 classifications (HS 2017 Edition) and the 15 consequential reclassifications (HS 2022 Edition) recommended by the Scientific Sub-Committee.
- (c) Annexes A/3 and C/3 – Possible reclassification of certain INN products consequential upon the Article 16 Recommendation of 23 June 2019. The Union shall approve the consequential (HS 2022 Edition) reclassifications of the 143 INN products agreed to by the Scientific Sub-Committee.
- (d) Annexes B/1 and C/6 – Decisions taken by the HS Committee at its 63rd and 64th Sessions and the WCO Council at its 133rd/134th Sessions, affecting the work of the Scientific Sub-Committee. The Union shall approve the reclassifications of “zilucoplan” and “etryptamine” agreed by the Scientific Sub-Committee, in subheadings 2933.79 and 2939.80, respectively.

The Union shall agree to all proposed classifications as they are in line with the current classification policy in the Union.

(2) Possible amendment of the Explanatory Notes to Chapter 29 in respect to the list of narcotic drugs, psychotropic substances and precursors Doc. NC2738Ea

The Union shall agree to the proposal to amend the HSEN to Chapter 29, in line with the advice of the Scientific Sub-Committee.

V. REPORT OF THE HS REVIEW SUB-COMMITTEE (Doc. NR1403E)

(1) Matters for decision (Doc. NC2709Ea)

- (a) Annexes D/6 and G/11 – Possible amendment to the Explanatory Note to heading 85.24 (HS 2022)
- (b) Annexes D/7 and G/12 – Possible amendments to the HS 2022 Explanatory Notes in respect of 3D printers
- (c) Annexes E/14 and G/19 – Amendment to the Explanatory Notes to heading 70.19 in respect of glass fibres (HS 2022)
- (d) Annexes E/1 to E/6, E/8 to E/13, E/15 to E/18, E/20, E/23 and G/1 to G/6, G/8, G/13 to G/18, G/21, G/22, G/24, G/27 – Possible amendment to the Explanatory Note to Sections I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XX and XXI.
- (e) Annexes E/23 and G/27 – Amendments to the Explanatory Notes to Chapter 97 in respect of certain cultural articles (HS 2022)
- (f) Annexes E/24 and G/28 – Amendments to the Explanatory Notes (GIRs)

The Union shall agree to all proposed amendments in the documents as they reflect the current classification policy in the Union.

- (2) Classification in HS 2022 of certain disposable or rechargeable personal electric vaporisers (Request by the Secretariat) Doc. NC2710Eb

The Union would classify product 1 in subheading 8543.70 in the HS2017 and in subheading 8543.40 in the HS2022. Product 2 shall be classified in heading 24.04 in the HS2022 using GIR 3(b), based on the essential character conferred by the e-liquid.

- (3) Classification in HS 2022 of certain collections and collectors' pieces of numismatic interest (Request by the Secretariat) Doc. NC2711Ea

The Union shall express the need for additional information on the products to determine classification.

The Union shall not agree with the proposal for amending the HSEN, pending clarification and guidance on how to differentiate between the new subheadings under heading 97.05.

- (4) Classification in HS 2022 of cartridges for 3D printers (Request by the Secretariat) Doc. NC2712Ea

The Union would classify the products in Chapter 39 according to the constituent material, in line with the ruling of the Court of Justice of the European Union in Case C-276/00. Additional information is needed to classify the products at subheading level. The proposed amendment to the HSEN shall not be supported, as the current practice in the Union is not to classify printer cartridges as parts of printers.

- (5) Classification in HS 2022 of a sheet lamination machine for additive manufacturing doc. NC2744Ea

The Union would classify the product in heading 84.85 (option II).

VI. REPORT OF THE PRESESSIONAL WORKING PARTY Doc. NC2714Ea and Annexes A to T

Subject to some editorial suggestions, the Union shall adopt the text presented in Annexes A to T with the following remarks:

- (1) Amendment to the Compendium of Classification Opinions to reflect the decision to classify a product in heading 18.06 (subheading 1806.32)

The Union shall suggest to delete the list of ingredients, not necessary for classification purposes.

- (2) Amendment to the Compendium of Classification Opinions to reflect the decision to classify two kinds of tobacco stems ("Cut rolled expanded stem tobacco (CRES)" and "Expanded tobacco stems (ETS)") in heading 24.03 (subheading 2403.99)

The Union shall insist to keep the text "cannot be smoked directly" as it was the decisive criterion for classification.

- (3) Amendment to the Compendium of Classification Opinions to reflect the decision to classify Solid Oxide Fuel Cells (SOFC) in heading 85.01 (subheading 8501.62)

The Union shall suggest using the product description from the boxed text of the initial working document (doc. NC2655E1b).

VII. REQUESTS FOR RE-EXAMINATION (RESERVATIONS)

- (1) Re-examination of the classification of certain dietary sip feeds (Products 1 to 5) (Request by the United States) Doc. NC2715Ea

The Union would classify the products as beverages in heading 22.02, in line with the ruling of the Court of Justice of the European Union in Case C-114/80 and Classification Opinions 2202.99/2-4.

- (2) Re-examination of the classification of a GPS running watch with wrist-based heart rate monitor (Requests by the United States and Japan) Doc. NC2716Ea

The Union would classify the product in subheading 9102.12 as a wrist-watch, in line with the CNEN for heading 91.02.

(3) Re-examination of the classification of Sterilizer (Request by Ukraine) Doc. NC2717Ea

The Union would classify the product in heading 84.19, as it is a specific heading for sterilisers. The change in temperature takes place and has an important effect on the sterilising process. The apparatus does not fulfil any mechanical functions.

(4) Re-examination of the classification of two products called "RF Generators and RF Matching Networks" (Request by South Korea) Doc. NC2718Ea, NC2745Eb, NC2747Ea

The Union would classify the products in heading 84.86 because they are identifiable machines used solely or principally for the manufacture of semiconductor devices.

VIII. FURTHER STUDIES

(1) Classification of edible insects (Proposal by the Secretariat) Doc. NC2719Ea

The Union shall support possible transfers from both headings 02.10 and 04.10 for product 1. Product 2 could be transferred either from heading 04.10 or Chapter 16. Product 3 could be transferred from Chapter 16. Product 4 could be transferred either from Chapter 16 or 21.

(2) Possible amendment of the Explanatory Note to heading 27.11 to clarify the classification of liquefied petroleum gas (LPG) (Proposal by the Secretariat) Doc. NC2720Ea

The Union shall support the creation of a subheading Explanatory Note to subheading 2711.19.

(3) Amendment of the Explanatory Notes to Rule 3 (b) to clarify the classification of sets Doc. NC2721Ea

The Union shall support keeping the *status quo* and current classification practices.

(4) Possible amendment of the Explanatory Note to heading 91.02 Doc. NC2722Ea

The Union would prefer to wait for a definitive decision on the classification in point VII.2 before advancing with amending the HSEN.

(5) Possible amendment of the Explanatory Note to heading 87.03 in relation to micro hybrid vehicles Doc. NC2723Ea

The Union shall support the amendment of the HSEN as it clarifies the classification of the new type of vehicles.

(6) Classification of mild hybrid vehicles Doc. NC2724Ea

The Union would classify the product in subheading 8703.40, as the electric motor is designed to give the vehicle a boost by supporting the engine operation.

(7) Classification of a waxy product (Request by Ecuador) Doc. NC2725Ea

The Union would classify the product in heading 34.04, as the laboratory analysis confirmed that the product had a waxy character.

(8) Possible amendment of the Explanatory Note to heading 95.03 (Proposal by the Union) Doc. NC2667Ea

The Union shall remain flexible to any additional editorial comments on the original EU proposal.

(9) Possible amendment of the Explanatory Note to heading 95.05 (Proposal by the Union) Doc. NC2668Ea

The Union shall remain flexible to any additional editorial comments on the original EU proposal.

- (10) Classification of certain essential oils put up for retail sale (Request by Costa Rica) Doc. NC2672Ea

The Union would classify the product in heading 33.01. This product is a lavender essential oil containing monoterpene alcohols, thus it is not deterpenated and it is covered by heading 33.01. It is obtained by steam distillation process thus compliant with the HSEN to heading 33.01.

- (11) Classification of two floor polishers (Request by Costa Rica) Doc. NC2673Ea

The Union would classify the products in heading 84.79. Due to their technical characteristics, they are not of the kind commonly used for domestic purposes and considering Note 4 (a) to Chapter 85 they should be classified in heading 84.79.

- (12) Classification of a “Self-Propelled Articulated Boom Lift” (Request by South Korea) Doc. NC2674Ea

The Union would classify the product in heading 84.28 based on Regulation (EC) No 738/2000 for a similar product.

- (13) Classification of certain food preparations (Request by the United States) Doc. NC2676Ea, NC2742Ea

The Union shall request additional information on all four products concerned to determine classification.

Product 1: protein contents. If very high (over 85 %), heading 35.04 could be considered. Based on current information, the product could be classified in subheading 2106.10 in line with Classification opinion 2106.90/5.

Product 2: the Union would classify it in heading 22.02 if directly drinkable, or heading 21.06 if to be diluted before drinking.

Product 3: the Union would classify it in subheading 2101.20, however, additional information about the caffeine content would be helpful.

Product 4: the product description is confusing, as it is not clear what the main ingredient is. If containing cocoa, it could be classified in heading 18.06, if not 19.05.

- (14) Classification of a “cutter/ripper” (Request by the Russian Federation) Doc. NC2677Ea

The Union shall note that the machine having many functions makes classification difficult to determine, and that it could be classified both in headings 84.30 and 84.32, thus in heading 84.32, using GIR 3(c).

- (15) Classification of certain new pneumatic tyres, of rubber, intended for vehicles used for the transportation of goods in construction, mining or industry (Request by the Russian Federation) Doc. NC2678Ea, NC2748Ea

The Union shall share the WCO Secretariat's advice, and classify both products in subheading 4011.20.

- (16) Classification of certain preparations of a kind used in animal feeding (Request by Canada) Doc. NC2679Ea, NC2743Ea

Based on the ruling of the Court of Justice of the European Union in Case C-144/15, the Union would classify the product in heading 23.09.

- (17) Classification of a product called “Tracing Light Box” (Request by Japan) Doc. NC2681Ea

The Union would classify the product in heading 94.05, as it has a multi-use function and is not equipped with any drawing instruments.

- (18) Classification of an electronic speed controller (Request by Tunisia) Doc. NC2682Ea

The Union would classify the product in heading 85.04, as suggested by the WCO Secretariat.

- (19) Possible amendment of the Explanatory Note to heading 27.10 (Proposal by Japan) Doc. NC2641Ea, NC2739Ea

The Union shall refrain to participate to discussions as the classification opinion from which this amendment stems cannot be applied in the Union due to the ruling of the Court of Justice of the European Union in Case C-330/13. It would be better to think about amending the HS in the future, and rearranging Note 2 to Chapter 27.

- (20) Possible misalignment between the English and French texts in the Explanatory Note to heading 85.01 Doc. NC2688Ea

The Union shall agree to the proposed amendment to use the French-language term “onduleur” as in other parts of the HS Nomenclature.

IX. NEW QUESTIONS

- (1) Classification of certain on-street garbage containers (Request by Tunisia) Doc. NC2726Ea

The Union would classify the products in heading 39.26 due to the larger size of the containers, not for domestic use. The Union notes that the product description should include the capacity of the containers in litres.

- (2) Classification of certain food preparations in liquid form (Request by Tunisia) Doc. NC2727Ea

The Union shall request more information concerning the contents of the products (water or juice, oily substances, other ingredients in addition to vitamins, dosage).

- (3) Classification of two products containing cannabidiol (CBD) (Request by the Secretariat) Doc. NC2728Ea

The Union shall propose to send the matter to the Scientific Sub-Committee, requesting information on (i) whether the products have enough active ingredients to give a therapeutic or prophylactic effect; and (ii) the minimum amount of CBD as active ingredient in any product to have a therapeutic or prophylactic effect.

- (4) Classification of dried fish subsequently treated with water (rehydrated dried fish) (Request by Norway) Doc. NC2729Ea

The Union could classify the product in Chapter 3, but more information is needed concerning if the flavour, texture of product were those of dried or fresh fish.

- (5) Classification of certain steam boiling generators for steam rooms (Request by Egypt) Doc. NC2730Ea

The Union would classify the products in heading 84.02 as proposed by the WCO Secretariat, in line with the heading text and HSEN to heading 84.02.

- (6) Classification of a product called “Soy bean flakes” (Request by Madagascar) Doc. NC2731Ea

The Union would classify the product in heading 23.04, similar to the product of Classification Opinion 2304.00/1.

- (7) Classification of a 2-burner ethanol stove (Request by Kenya) Doc. NC2732Ea

The Union would classify the product in subheading 7321.12, as ethanol fuel is in liquid form at room temperature and fits therefore with the subheading text.

- (8) Classification of an interactive kiosk for receiving complaints (Request by Egypt) Doc. NC2733Ea

The Union shall request additional information: whether the product could function and how with an USB device, or whether it can be used only via touch screen.

XI. ADDITIONAL LIST

- (1) Classification of a product called “baby corn cobs” (Request by the EU) Doc. NC2736Ea

The Union has requested a Classification Opinion.

- (2) Classification of a diesel power generating set with dual power rating (Request by Ghana) Doc. NC2737Ea
The Union would classify the product in subheading 8502.13.

 - (3) Classification of a TFT-LCD module (Request by South Korea) Doc. NC2740Ea
In line with Commission Regulation (EC) No 957/2006, Commission Implementing Regulations (EU) No 1201/2011 and No 1202/2011, and considering Note 2 (b) to Section XVI, the Union would classify the product in subheading 8529.90.

 - (4) Deletion of Classification Opinions 8528.69/1 and 8528.69/2 Doc. NC2741Ea
As the products are not anymore on the market, the Union shall support the deletion of those Classification Opinions.

 - (5) Classification of a product called “partially defatted coconut powder” (Request from the Union) Doc. NC2746Ea
The Union has requested a Classification Opinion.’
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