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(<sup>1</sup>) Text with EEA relevance.



Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

### **GUIDELINES**

 Π

(Non-legislative acts)

# REGULATIONS

### COMMISSION IMPLEMENTING REGULATION (EU) 2022/964

### of 10 June 2022

### granting a Union authorisation for the biocidal product family 'SOPUROXID'

(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 (<sup>1</sup>), and in particular the first subparagraph of Article 44(5) thereof,

Whereas:

- (1) On 1 September 2017, SOPURA N.V. submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'SOPUROXID' of product-types 2, 3 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-KV033704-17 in the Register for Biocidal Products.
- (2) 'SOPUROXID' contains peracetic acid, 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 2020, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').
- (4) On 31 March 2021, the Agency submitted to the Commission an opinion (<sup>2</sup>), including the draft summary of the biocidal product characteristics ('SPC') of 'SOPUROXID' 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 'SOPUROXID' is a 'biocidal product family' within the meaning of Article 3(1), point (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 28 April 2021, 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 'SOPUROXID'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

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

<sup>(2)</sup> ECHA opinion of 4 March 2021 on the Union authorisation of 'SOPUROXID' (ECHA/BPC/279/2021), https://echa.europa.eu/bpcopinions-on-union-authorisation

HAS ADOPTED THIS REGULATION:

### Article 1

A Union authorisation with authorisation number EU-0026179-0000 is granted to SOPURA N.V. for the making available on the market and use of the biocidal product family 'SOPUROXID' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 12 July 2022 until 30 June 2032.

### 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, 10 June 2022.

For the Commission The President Ursula VON DER LEYEN

### ANNEX

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

#### SOPUROXID

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

Product type 3 - Veterinary hygiene (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0026179-0000

R4BP asset number: EU-0026179-0000

### PART I

### FIRST INFORMATION LEVEL

### 1. ADMINISTRATIVE INFORMATION

### 1.1. Family name

Name SOPUROXID
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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)	
	PT03 - Veterinary hygiene (Disinfectants)	
	PT04 - Food and feed area (Disinfectants)	

### 1.3. Authorisation holder

Name and address of the authorisation holder	Name	SOPURA	
	Address	rue de Trazegnies 199, 6180 COURCELLES Belgium	
Authorisation number	EU-0026179-0000		
R4BP asset number	EU-0026179-0000		
Date of the authorisation	12 July 2022		
Expiry date of the authorisation	30 June 2032		

# 1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	SOPURA N.V.
Address of manufacturer	Rue de Trazegnies 199, 6180 COURCELLES Belgium
Location of manufacturing sites	Rue de Trazegnies 199, 6180 COURCELLES Belgium

Name of manufacturer	SOPURA QUIMICA
Address of manufacturer	Poligon "La Canaleta", Avinguda Júpiter 7, 25300 TARREGA Spain
Location of manufacturing sites	Poligon "La Canaleta", Avinguda Júpiter 7, 25300 TARREGA Spain

Name of manufacturer	HYPRED SAS (KERSIA Group)
Address of manufacturer	55, Boulevard Jules Verger (BP 10180), 35803 DINARD France
Location of manufacturing sites	55, Boulevard Jules Verger (BP 10180), 35803 DINARD France Niepruszewo, ul. Kasztanowa, 64-320 Buk Poland

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

Active substance	Peracetic acid	
Name of manufacturer	SOPURA N.V.	
Address of manufacturer	Rue de Trazegnies 199, 6180 COURCELLES Belgium	
Location of manufacturing sites	Rue de Trazegnies 199, 6180 COURCELLES Belgium	

Active substance	Peracetic acid
Name of manufacturer	SOPURA QUIMICA
Address of manufacturer	Poligon "La Canaleta", Avinguda Júpiter 7, 25300 TARREGA Spain
Location of manufacturing sites	Poligon "La Canaleta", Avinguda Júpiter 7, 25300 TARREGA Spain

Active substance	Peracetic acid
Name of manufacturer	HYPRED SAS (KERSIA Group)
Address of manufacturer	55, Boulevard Jules Verger (BP 10180), 35803 DINARD France
Location of manufacturing sites	55, Boulevard Jules Verger (BP 10180), 35803 DINARD France Niepruszewo, ul. Kasztanowa, 64-320 Buk Poland

### 2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name IUPAC name		Europei euro	CAS number	FC much an	Content (%)	
	Function	CAS number	EC number	Min	Max	
Peracetic acid		Active Substance	79-21-0	201-186-8	3,2	15,0
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,2	24,04
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	16,5	23,5
Acetic acid		Non-active substance	64-19-7	200-580-7	5,5	16,7

### 2.2. Type(s) of formulation

Formulation(s)	SL - Soluble concentrate
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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 SPC1
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### 1.2. Suffix to the authorisation number

### 1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
	PT03 - Veterinary hygiene (Disinfectants)
	PT04 - Food and feed area (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
Peracetic acid		Active Substance	79-21-0	201-186-8	5,0	5,0
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,2	24,04
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	16,5	22,0
Acetic acid		Non-active substance	64-19-7	200-580-7	5,5	9,55

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

Formulation(s)	SL - Soluble concentrate
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### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May intensify fire; oxidiser May be corrosive to metals. Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. Causes severe skin burns and eye damage. Causes serious eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.
Precautionary statements	<ul> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.</li> <li>No smoking.</li> <li>Wear protective gloves.</li> <li>Wear eye protection.</li> <li>Wear face protection.</li> <li>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.</li> <li>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</li> <li>Immediately call a POISON CENTER/doctor.</li> <li>Take any precaution to avoid mixing with combustibles.</li> <li>Avoid breathing vapours.</li> <li>Wash hands thoroughly after handling.</li> <li>Do not eat, drink or smoke when using this product.</li> <li>Use only outdoors or in a well-ventilated area.</li> <li>Specific treatment (see information on this label).</li> <li>Rinse mouth.</li> <li>Wash contaminated clothing before reuse.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</li> <li>IF ON SKIN: Wash with plenty of water.</li> </ul>

<ul> <li>IF INHALED: Remove person to fresh air and keep comfortable for Take off immediately all contaminated clothing. And wash it before Store locked up.</li> <li>Store in a well-ventilated place. Keep container tightly closed. Dispose of contents to in accordance with local/regional/national regulations.</li> <li>Wear protective clothing.</li> <li>Dispose of container to in accordance with local/regional/national regulations.</li> <li>Keep cool.</li> <li>Avoid release to the environment.</li> <li>Collect spillage.</li> <li>IF ON SKIN (or hair): Take off immediately all contaminated cloth with shower.</li> <li>Avoid breathing spray.</li> <li>Do not breathe spray.</li> <li>Do not breathe vapours.</li> </ul>	ore reuse.
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### 4. AUTHORISED USE(S) OF THE META SPC 1

# 4.1. Use description

Table 1

# Use # 1 – Disinfection of surfaces in industrial, public and non-medical healthcare areas - manual treatment (mopping)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In Industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by manual treatment (mopping) with prior cleaning
Application method(s)	Method: Manual treatment (mopping). Detailed description: Diluted product is applied by mopping with the appropriate tool (e.g. flat mop or cleaning cloths). After application, the diluted product is drained.
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: Non-medical healthcare areas With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) at Room Temperature in 5 min contact time. Application rate: 20 mL/m <sup>2</sup> Use other than in

	HEALTHCARE With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Application rate: 30 mL/m <sup>2</sup> Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.1.1. Use-specific instructions for use

Items to be disinfected by mopping have to stay sufficiently wet during the required contact time to allow optimal disinfection.

#### 4.1.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing and loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Re-entry is only permitted once the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AEC). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by the authorization holder).

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

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

# 4.2. Use description

Table 2

# Use # 2 – Disinfection of surfaces in industrial, public and non-medical healthcare areas. - manual treatment (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)	Common name: Bacteria Development stage: Common name: Yeasts
	Development stage:
Field(s) of use	Indoor In Industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by manual treatment (spraying) with prior cleaning
Application method(s)	Method: Manual treatment (spraying)
	Detailed description: Diluted product is applied by spraying using a small spraying can
Application rate(s) and frequency	Application Rate: -
	Dilution (%): Against bacteria and yeasts: Non-medical healthcare areas: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) at Room Temperature in 5 min contact time. Application rate: 20 mL/m <sup>2</sup> . Use other than in HEALTHCARE With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Application rate: 30 mL/m <sup>2</sup> .
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
111av11a1	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.2.1. Use-specific instructions for use

See general directions for use

4.2.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

"The treated surface should not be allowed to dry prior to rinsing.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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 See general directions for use.
- 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.3. Use description

### Table 3

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In pharmaceutical and cosmetic industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Method: By CIP procedure Detailed description: Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.

Use # 3 - Clean in Place (CIP) in the pharmaceutical and cosmetic industry

Application rate(s) and frequency	Application Rate: -
	Dilution (%): Against bacteria and yeasts: With 0,032 % PAA (Dilution of the product at 0,64 % i.e. 640 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.3.1. Use-specific instructions for use

See general directions for use

4.3.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Rinse the pump and disconnect it from the installation before maintenance"

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 See general directions for use.
- 4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.4. Use description

### Table 4

# Use # 4 – Surface disinfection in greenhouses via spraying by user with personal enclosure (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In greenhouses: Disinfection of hard/non-porous surfaces by spraying
Application method(s)	Method: Open system: spray treatment
	Detailed description: Diluted product is automatically applied in all directions via a spraying device
	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.4.1. Use-specific instructions for use

See general directions for use.

### 4.4.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

- 4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.5. Use description

Table 5

# Use # 5 – Surface disinfection in greenhouses via spraying by user without personal enclosure (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In greenhouses: Disinfection of hard/non-porous surfaces by spraying
Application method(s)	Method: Open system: spray treatment
	Detailed description: Diluted product is automatically applied in all directions via a spraying device.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.5.1. Use-specific instructions for use

See general directions for use.

4.5.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.5.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.6. Use description

#### Table 6

# Use # 6 – Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning.
Application method(s)	Method: Open system: immersion
	Detailed description: The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Application Rate: -
	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.6.1. Use-specific instructions for use

See general directions for use.

### 4.6.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the post-application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

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

See general directions for use.

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

See general directions for use.

- 4.6.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.7. Use description

Table 7

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor
	In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Open system: spray treatment
	Detailed description: The diluted product is manually sprayed on the surfaces/equipment using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
1 /	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time.
	Number and timing of application: /

# Use # 7 – Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.7.1. Use-specific instructions for use

See general directions for use.

4.7.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

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

See general directions for use.

- 4.7.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.7.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.8. Use description

### Table 8

# Use # 8 – Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)

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	Not relevant

Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description: Diluted product is applied by spraying in an automated way Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Application Rate: -
irequency	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.8.1. Use-specific instructions for use

See general directions for use.

### 4.8.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

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

See general directions for use.

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

See general directions for use.

4.8.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.9. Use description

### Table 9

# Use # 9 – Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: By spraying. Detailed description: Diluted product is applied by spraying in an automated way without any operator being present
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

4.9.1. Use-specific instructions for use

See general directions for use.

4.9.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

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

See general directions for use.

- 4.9.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.9.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.10. Use description

Table 10

#### Use # 10 – Disinfection of animal housing – via low-pressure spraying by user with personal enclosure

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing: Disinfection of hard/non-porous surfaces by spraying with prior cleaning

Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure manual spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Application Rate: Between 20 and 300 mL/m <sup>2</sup>
	Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 1,28 % i.e. 1 280 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.10.1. Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

### 4.10.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.10.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.11. Use description

### Table 11

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Open system: spray treatment
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure automatic spraying via a spraying device
Application rate(s) and frequency	Application Rate: Between 20 and 300 mL/m <sup>2</sup>
1	Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 1,28 % i.e.1 280 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional

# Use # 11 – Disinfection of animal housing via low-pressure manual spraying by user without personal enclosure

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.11.1. Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

4.11.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.11.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

### 4.12. Use description

Table 12

Use # 12 – Disinfection o	f boots in foo	tbaths in anima	l housing/	husbandries

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

Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Viruses Development stage:
Field(s) of use	Indoor in animal housing/husbandries: Disinfection of boots by dipping (not for walk-through) with prior cleaning.
Application method(s)	Method: Dipping
	Detailed description:
	Diluted product is put in the footbath
	No rinse needed
Application rate(s) and frequency	Application Rate: -
1 /	Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 1,28 % i.e. 1 280 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.12.1. Use-specific instructions for use

See general directions for use.

### 4.12.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase. When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.12.3. 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.

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

See general directions for use.

4.12.5. 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.

### 4.13. Use description

Table 13

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
	Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning
Application method(s)	Method: Soaking. Detailed description: The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 1,28 % i.e. 1 280 mL/100 L) in 60 min contact time. Number and timing of application:

### Use # 13 – Disinfection of equipment by dipping

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

4.13.1. Use-specific instructions for use

See general directions for use.

4.13.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance

4.13.3. 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.

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

See general directions for use.

4.13.5. 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.

### 4.14. Use description

#### Table 14

# Use # 14 – Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	

Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description: Diluted product is sprayed on the surfaces in an automated way without any operator being present
Application rate(s) and	Application Rate: -
frequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging	HDPE with screw and venting caps (weight depends on density of product):
material	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.14.1. Use-specific instructions for use

See general directions for use.

### 4.14.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance

The treated surface should not be allowed to dry prior to rinsing.

4.14.3. 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.

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

See general directions for use.

4.14.5. 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.

### 4.15. Use description

### Table 15

Product type	PT04 - Food and feed area (Disinfectants)	
Where relevant, an exact description of the authorised use	Not relevant	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage: Common name: Bacteriophages Development stage:	
Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning	

Use # 15 – Disinfection of equipment in the food and beverage industry by immersion

Application method(s)	Method: Soaking. Detailed description: The concentrated product is pumped in a soaking bath and diluted to the desired
Application rate(s) and frequency	use concentration, before immersion of items to be disinfected Application Rate: -
nequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.15.1. Use-specific instructions for use

See general directions for use.

### 4.15.2. Use-specific risk mitigation measures

### Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.15.3. 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.

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

See general directions for use.

4.15.5. 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.

### 4.16. Use description

### Table 16

# Use # 16 – Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Method: Closed system
	Detailed description:
	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations.
	After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.

Application rate(s) and frequency	Application Rate: -
	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.16.1. Use-specific instructions for use

See general directions for use.

### 4.16.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Rinse the pump and disconnect it from the installation before maintenance

4.16.3. 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.

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

See general directions for use.

4.16.5. 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.

# 4.17. Use description

### Table 17

# Use # 17 – Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device).
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.17.1. Use-specific instructions for use

See general directions for use.

4.17.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

4.17.3. 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.

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

See general directions for use.

4.17.5. 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.

### 4.18. Use description

### Table 18

# Use # 18 – Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:

	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

### 4.18.1. Use-specific instructions for use

See general directions for use.

### 4.18.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance

The treated surface should not be allowed to dry prior to rinsing.

4.18.3. 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.

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

See general directions for use.

4.18.5. 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.

## 4.19. Use description

Table 19

Product type	PT04 - Food and feed area (Disinfectants)				
Where relevant, an exact description of the authorised use					
Target organism(s) (including development stage)	Common name: Bacteria Development stage:				
	Common name: Yeasts Development stage:				
	Common name: Bacterial spores Development stage:				
	Common name: Viruses Development stage:				
	Common name: Bacteriophages Development stage:				
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning				
Application method(s)	Method: Manual application - spraying.				
	Detailed description: Diluted product is manually applied by low-pressure spraying, only downwards				
	and horizontal.				

## Use # 19 – Disinfection of surfaces and equipment by low pressure spraying, manually

Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup> Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.19.1. Use-specific instructions for use

See general directions for use.

#### 4.19.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

4.19.3. 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.

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

See general directions for use.

4.19.5. 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.

# 4.20. Use description

## Table 20

# Use # 20 – Disinfection of surfaces and equipment by low pressure spraying, automatically

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	The diluted product is sprayed on the equipment, on conveyor belt, automatically.
	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device). Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.20.1. Use-specific instructions for use

See general directions for use.

## 4.20.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

RPE are not mandatory during the application phase, on the condition that the operator remains in the control room and do not enter the treated area.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

4.20.3. 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.

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

See general directions for use.

4.20.5. 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.

## 4.21. Use description

### Table 21

# Use # 21 – Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-

Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage: Common name: Bacteriophages			
	Development stage:			
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning			
Application method(s)	Method: Spraying			
	Detailed description:			
	The diluted solution is sprayed on the surfaces in an automated way without any user being present.			
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>			
frequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.			
	Number and timing of application: /			
Category(ies) of users	Industrial Professional			
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):			
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.			

# 4.21.1. Use-specific instructions for use

See general directions for use.

# 4.21.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) is not mandatory during the application phase, on condition that the operator do not enter the treated area and remains in the control room.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

The treated surface should not be allowed to dry prior to rinsing.

4.21.3. 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.

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

See general directions for use.

4.21.5. 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.

## 4.22. Use description

#### Table 22

Product type	PT04 - Food and feed area (Disinfectants)			
Where relevant, an exact description of the authorised use	-			
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage:			
	Common name: Bacteriophages Development stage:			
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning			

Use # 22 – Disinfection of inner surfaces (pipelines, tanks, vessels, ...) by CIP

Application method(s)	Method: Closed system Detailed description: Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations.			
	After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.			
Application rate(s) and frequency	Application Rate: - Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0,96 % i.e. 960 mL/100 L) in 15 min contact time , efficient use temperature from + 4 °C up to Room Temperature Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 1,28 % i. e. 1 280 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature. For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application: /			
Category(ies) of users	Industrial Professional			
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.			

## 4.22.1. Use-specific instructions for use

See general directions for use.

## 4.22.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading phase.

Respiratory protection:

Rinse the pump and disconnect it from the installation before maintenance"

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

4.22.3. 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.

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

See general directions for use.

4.22.5. 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.

# 4.23. Use description

## Table 23

Product type	PT04 - Food and feed area (Disinfectants)				
Where relevant, an exact description of the authorised use	-				
Target organism(s) (including development stage)	Common name: Bacteria Development stage:				
	Common name: Yeasts Development stage:				
Field(s) of use	Indoor In food industry: Disinfection of water (in clean conditions) used for rinsing of recycled items = Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recontamination and in an extent to avoid cross-contamination of inner bottle surfaces				
Application method(s)	Method: Closed system				
	Detailed description:				
	Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.				
Application rate(s) and	Application Rate: -				
frequency	Dilution (%): Against bacteria and yeasts: With 0.008 % PAA (Dilution of the product at 0.16 % i.e. 160 mL/100 L) at Room Temperature in 15 min contact time.				
	Number and timing of application: /				
Category(ies) of users	Industrial Professional				
Pack sizes and packaging material HDPE with screw and venting caps (weight depends on density of p Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 20 bottles, bulk delivery.					

# Use # 23 – Disinfection of water used for rinsing of recycled items during the washing process

4.23.1. Use-specific instructions for use

See general directions for use.

4.23.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection: Not mandatory.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

4.23.3. 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.

- 4.23.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.23.5. 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

- 1. All the surfaces to be disinfected must be cleaned before the disinfection procedure
- 2. Disinfection cycle:
  - Products must be diluted in potable water before use.
  - Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
  - Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system. For exceptions, please refer to the description of application method related to each use.

Only for use in areas that are inaccessible to the general public and companion animals.

No access for the general public during treatment.

Disinfection procedures by CIP: Final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

Disinfection procedures **by dipping**: The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily.

Disinfection procedures **by spraying:** the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

The Application Rate for spraying of diluted product must be between 20 and 30 mL/m<sup>2</sup>

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

### 5.2. Risk mitigation measures

#### Dermal protection:

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

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

#### Indirect effects

The two theoretical products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.

Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to selfaccelerated, exothermic decomposition and the formation of oxygen.

In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

#### First aid measures

#### Ø General advice

Move out of dangerous area.

Take care of your own personal safety.

Take off immediately all contaminated clothing.

#### Ø Inhalation

Take affected persons out into the fresh air.

Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.

If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

## Ø Skin contact

After contact with skin, wash immediately with plenty of water.

Consult a physician.

Take off immediately all contaminated clothing.

Immediately rinse contaminated or saturated clothing with water.

## Ø Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Protect unharmed eye.

Continue rinsing process with eye rinsing solution.

Call ambulance (caustic burn of the eyes)

Immediate further treatment in ophthalmic hospital/ophthalmologist.

Continue rinsing eye until arrival at ophthalmic hospital.

#### Ø Ingestion

Do not induce vomiting.

Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.

Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.

Notify ambulance immediately (key word: acid burn).

## Ø Notes to physician

Therapy as for chemical burn.

Following inhalation:

Formation of a toxic lung oedema is possible if product continues to be inhaled despite acute irritative effect (e.g. if it is not possible to leave the danger area).

Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).

If substance has been swallowed:

Aspiration hazard.

Risk of gaseous embolisms.

In case of excessive strain on the stomach due to gas evolution, insert siphon tube.

Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.

If necessary, suck away leftover substance.

Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

#### Emergency measures to protect the environment

Observe regulations on prevention of water pollution (collect, dam up, cover up).

Do not allow to run into water channels, surface water or into the ground.

#### Ø Methods for cleaning up

Clean contaminated surface thoroughly; recommended cleaning agent is water.

In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemi-sorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

## Ø Additional advice

Make safe or remove all sources of ignition.

Isolate defective containers immediately, if possible and safe to do.

Shut off leak, if possible and safe to do.

Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).

Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).

Product taken out should not be returned into container.

Never return spilled product into its original container for re-use (risk of decomposition).

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

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place Keep products away from direct sunlight, source of heat and ignition

The shelf life of the biocidal product is 6 months.

The products must be stored at temperatures below + 30 °C.

## 6. OTHER INFORMATION

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment:

**PAA**: AECinhal =  $0.5 \text{ mg/m}^3$ 

**HP**: AECinhal =  $1,25 \text{ mg/m}^3$ 

## 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)	SOPUROXID 5		Marke	Market area: EU			
	HyPro Biocide 5-22		Market area: EU				
	AGRIOXID 5		Marke	Market area: EU			
	TECMA CUAR HPA Ma		Marke	arket area: EU			
Authorisation number	EU-0026179-0001 1-1						
Common name	IUPAC name	Function		CAS number	EC number	Content (%)	
Peracetic acid		Active Substance		79-21-0	201-186-8	5,0	
Sulphuric acid		Non-active substance		7664-93-9	231-639-5	0,2	
Hydrogen peroxide		Non-active substance		7722-84-1	231-765-0	22,0	
Acetic acid		Non-active substance		64-19-7	200-580-7	9,55	

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

Trade name(s)	SOPUROXID 5C	Market area: EU		
	DEPTIL TR 5	Market area: EU		
	DIS OXI-5+	Market area: EU		
	ANTI-GERM DES OXI-50 TC	Market area: EU		
	Peracid ATR +	Market area: EU		

	FOR-Acid TR +		Market area: EU			
	X-CID TR 50 +		Market area: EU			
Authorisation number	EU-0026179-0002 1-1					
Common name	IUPAC name	Function		CAS number	EC number	Content (%)
Peracetic acid		Active Substance		79-21-0	201-186-8	5,0
Sulphuric acid		Non-active substance		7664-93-9	231-639-5	24,04
Hydrogen peroxide		Non-active substance		7722-84-1	231-765-0	16,5
Acetic acid		Non-active substance		64-19-7	200-580-7	5,8

## META SPC 2

## 1. META SPC 2 ADMINISTRATIVE INFORMATION

# 1.1. Meta SPC 2 identifier

## 1.2. Suffix to the authorisation number

|--|

# 1.3. **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) PT03 - Veterinary hygiene (Disinfectants)
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## 2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active Substance	79-21-0	201-186-8	3,2	3,2
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,8	1,0

Hydrogen peroxide	Non-active substance	7722-84-1	231-765-0	23,5	23,5
Acetic acid	Non-active substance	64-19-7	200-580-7	6,45	7,5

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

Formulation(s) SL	I Soluble concentrate
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# 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	May intensify fire; oxidiser May be corrosive to metals. Causes severe skin burns and eye damage. Causes serious eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects. Harmful if swallowed. Harmful in contact with skin.
Precautionary statements	<ul> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources <ul> <li>No smoking.</li> <li>Wear face protection.</li> </ul> </li> <li>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.</li> <li>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</li> <li>Immediately call a POISON CENTER/doctor.</li> <li>Wear eye protection.</li> <li>Wear eye protection.</li> <li>Wear protective gloves.</li> <li>Take any precaution to avoid mixing with combustibles.</li> <li>Avoid breathing vapours.</li> <li>Wash hands thoroughly after handling.</li> <li>Do not eat, drink or smoke when using this product.</li> <li>Use only outdoors or in a well-ventilated area.</li> <li>Specific treatment (see information on this label).</li> <li>Rinse mouth.</li> <li>Wash contaminated clothing before reuse.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</li> <li>IF ON SKIN: Wash with plenty of water.</li> <li>IF INHALED: Remove person to fresh air and keep comfortable for breathing.</li> <li>Take off contaminated clothing. And wash it before reuse.</li> <li>Store locked up.</li> <li>Store in a well-ventilated place. Keep container tightly closed.</li> <li>Dispose of contents to in accordance with local/regional/national/international regulations.</li> <li>Wear protective clothing.</li> <li>Dispose of container to in accordance with local/regional/national/international regulations.</li> <li>Keep cool.</li> <li>Avoid release to the environment.</li> <li>Collect spillage.</li> <li>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with shower.</li> </ul>

Avoid breathing spray.
Do not breathe spray.
Do not breathe vapours.
1

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

4.1. Use description

## Table 24

# Use # 1 – Room Disinfection by fogging - In industrial, public and non-medical healthcare areas. (pharmaceutical and cosmetic industry)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage:		
Field(s) of use	Indoor In industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by fogging.		
Application method(s)	Method: Fogging Detailed description: By fogging with the diluted product		
Application rate(s) and frequency	Application Rate: - Dilution (%): Active against bacteria (including bacterial spores) and yeasts: With 5,6 mL/m <sup>3</sup> (Dilution of the product at 40 % i.e. 40 L/100 L i.e. 1,28 % PAA) at Room Temperature in 2h contact time (after diffusion) Number and timing of application:		
Category(ies) of users	Industrial Professional		
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.		

<sup>4.1.1.</sup> Use-specific instructions for use

See general directions for use.

4.1.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

- 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.2. Use description

Table 25

# Use # 2 – Room Disinfection by fogging - In agriculture & horticulture areas (in absence of plants - for general hygiene purpose only)

Product type	PT02 - Disinfectants and algaecides not intended for direct application to huma or animals (Disinfectants)	
Where relevant, an exact description of the authorised use		
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:	
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces by fogging with prior cleaning	
Application method(s)	Method: Fogging Detailed description: By fogging with the diluted product	

Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 5,6 mL/m <sup>3</sup> (Dilution of the product at 40 % i.e. 40 L/100 L i.e. 1,28 % PAA) at Room Temperature in 2h contact time (after diffusion) Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.2.1. Use-specific instructions for use

See general directions for use.

#### 4.2.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

# 4.3. Use description

Table 26

## Use # 3 – Room Disinfection by fogging – In animal housing

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In animal housing: Disinfection of hard/non-porous surfaces by fogging with prior cleaning
Application method(s)	Method: Fogging
	Detailed description:
	By fogging with the diluted product
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 5,6 mL/m <sup>3</sup> (Dilution of the product at 40 % i.e. 40 L/100 L i.e. 1,28 % PAA) at Room Temperature in 2h contact time (after diffusion)
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

# 4.3.1. Use-specific instructions for use

See general directions for use.

## 4.3.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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 See general directions for use.
- 4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

## 4.4. Use description

#### Table 27

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
Field(s) of use	Indoor In food/feed areas (storage rooms): Disinfection of hard/non-porous surfaces by fogging.
Application method(s)	Method: Fogging
	Detailed description:
	By fogging with the diluted product
Application rate(s) and frequency	Application Rate: -
	Dilution (%): Active against bacteria (including bacterial spores) and yeasts With 5,6 mL/m <sup>3</sup> (Dilution of the product at 40 % i.e. 40 L/100 L i.e. 1,28 % PAA) at Room Temperature in 2h contact time (after diffusion)

#### Use # 4 - Room Disinfection by fogging - In storage rooms with special device in storage cellar or room

	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.4.1. Use-specific instructions for use

See general directions for use.

## 4.4.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

- 4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 5. GENERAL DIRECTIONS FOR USE (<sup>2</sup>) OF THE META SPC 2

## 5.1. Instructions for use

1. All the surfaces to be disinfected must be cleaned before the disinfection procedure.

For exceptions, please refer to the description of application method related to each use.

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

- 2. Disinfection cycle:
  - Products must be diluted in potable water before use.
  - Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
  - Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system. For exceptions, please refer to the description of application method related to each use.

Meta SPC2: Disinfection procedures by fogging

The product SOPUROXID 3.2 is a liquid disinfectant to be applied (after dilution at 40 %) by fogging for airborne surface disinfection and to be used indoor by professional users only.

Always check compatibility of the products with the hard/non-porous surfaces to be disinfected.

The product SOPUROXID 3.2 has been developed and demonstrated as efficacious (via efficacy studies performed according to the NF T 72 281 standard), using one device HYSPRAY, for rooms with a volume between 30 & 150 m<sup>3</sup> (volume per application and per device) with a flow rate of 0,047 mL/min/m<sup>3</sup>.

The use of other devices is possible. They must be designed to work with PAA-based products and to ensure a fog production able to stay suspended in the air and provided that these devices meet following characteristics:

- 1) Particle (medium droplet) size: between 1 and 15 µm
- 2) Flow rate: 0,047 mL/min/m<sup>3</sup>
- 3) Application rate: 5,6 mL/m<sup>3</sup>
- 4) Room volume between 30 and 150 m<sup>3</sup> per application and per device (i.e. diffusion time between 5 and 30 min)
- Airborne disinfection should be done only after thorough cleaning and rinsing.

The surfaces to be disinfected should be dried before the disinfection procedure. Please pay attention to open the cupboard doors. Please check the temperature and the relative room humidity (to be set between 40 and 80 %) to obtain an optimal level for the product efficiency.

The room where the fogging activity takes place is tightly sealed during fogging, no user is present:

Before the start of the disinfection cycle by fogging, the treated room is sealed. All the safety tasks for the implementation of decontamination are entrusted to an user who has completed the necessary training. Among them, first step is shutting down the air handling units and closing the air intake and return, so the product is not spread in the other rooms. The door or doors to the outside of the area are then locked and, if the joints are not tight enough, they are taped to seal. An orange tape, or bright colour, is preferably chosen to attract attention and a sign "Access ban, room disinfection in progress" is put on. Only for use in areas that are inaccessible to the general public and companion animals".

— The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter. Each device or specific installation is systematically validated when it is set up.

### 5.2. **Risk mitigation measures**

Dermal protection:

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

+ Additional specific RMM for **fogging** applications:

Only for use in areas that are inaccessible to the general public and companion animals.

 After disinfection product's application by fogging & required contact time for optimal disinfection (2h), the room must be ventilated, preferably by mechanical ventilation at least for 60 min.

The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by the authorisation holder within the product information).

- After ventilation, re-entry in the disinfected area is only permitted after the air concentrations of peracetic acid and hydrogen peroxide have been checked and seen as dropped below the respective reference values (AEC):
- The air concentration of PAA must have dropped to 0,5 mg/m<sup>3</sup>.

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

#### Indirect effects

The two products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.

Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to self-accelerated, exothermic decomposition and the formation of oxygen.

In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

First aid measures

#### Ø General advice

Move out of dangerous area.

Take care of your own personal safety.

Take off immediately all contaminated clothing.

### Ø Inhalation

Take affected persons out into the fresh air.

Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.

If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

#### Ø Skin contact

After contact with skin, wash immediately with plenty of water.

Consult a physician.

Take off immediately all contaminated clothing.

Immediately rinse contaminated or saturated clothing with water.

#### Ø Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Protect unharmed eye.

Continue rinsing process with eye rinsing solution.

Call ambulance (caustic burn of the eyes)

Immediate further treatment in ophthalmic hospital/ophthalmologist.

Continue rinsing eye until arrival at ophthalmic hospital.

#### Ø Ingestion

Do not induce vomiting.

Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.

Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.

Notify ambulance immediately (key word: acid burn).

#### Ø Notes to physician

Therapy as for chemical burn.

Following inhalation:

Formation of a toxic lung oedema is possible if product continues to be inhaled despite acute irritative effect (e.g. if it is not possible to leave the danger area).

Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).

If substance has been swallowed:

Aspiration hazard.

Risk of gaseous embolisms.

In case of excessive strain on the stomach due to gas evolution, insert siphon tube.

Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.

If necessary, suck away leftover substance.

Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

Emergency measures to protect the environment

Observe regulations on prevention of water pollution (collect, dam up, cover up).

Do not allow to run into water channels, surface water or into the ground.

#### Ø Methods for cleaning up

Clean contaminated surface thoroughly; recommended cleaning agent is water.

In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemi-sorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

### Ø Additional advice

Make safe or remove all sources of ignition.

Isolate defective containers immediately, if possible and safe to do.

Shut off leak, if possible and safe to do.

Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).

Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).

Product taken out should not be returned into container.

Never return spilled product into its original container for re-use (risk of decomposition).

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

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place Keep products away from direct sunlight, source of heat and ignition

The shelf life of the biocidal product is 6 months.

The products must be stored at temperatures below + 30 °C.

## 6. OTHER INFORMATION

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment:

**PAA**: AECinhal =  $0.5 \text{ mg/m}^3$ 

**HP**: AECinhal =  $1,25 \text{ mg/m}^3$ 

#### 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)	SOPUROXID 3.2		Marke	Market area: EU			
	HyPro Biocide	HyPro Biocide 3.2-23 Mar		Market area: EU			
Authorisation number	EU-0026179-0	003 1-2					
Common name	IUPAC name	Function		CAS number	EC number	Content (%)	
Peracetic acid		Active Substance		79-21-0	201-186-8	3,2	
Sulphuric acid		Non-active substance		7664-93-9	231-639-5	0,8	
Hydrogen peroxide		Non-active substance		7722-84-1	231-765-0	23,5	
Acetic acid		Non-active substance		64-19-7	200-580-7	6,45	

## META SPC 3

## 1. META SPC 3 ADMINISTRATIVE INFORMATION

## 1.1. Meta SPC 3 identifier

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## 1.2. Suffix to the authorisation number

Number 1-5
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# 1.3. **Product type(s)**

P104 - Food and feed area (Disinfectants) PT03 - Veterinary hygiene (Disinfectants)	Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants) 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 nome	IUPAC name	Function	CAS number	EC number	Cont	ent (%)
Common name	IOPAC name	Function	CAS number	EC number	Min	Max
Peracetic acid		Active Substance	79-21-0	201-186-8	3,2	3,2
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,6	1,0
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	23,5	23,5
Acetic acid		Non-active substance	64-19-7	200-580-7	5,5	7,1

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

Formulation(s)	SL - Soluble concentrate
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### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May intensify fire; oxidiser May be corrosive to metals. Harmful if swallowed. Harmful in contact with skin. Causes severe skin burns and eye damage. Causes serious eye damage. May cause respiratory irritation. Very toxic to aquatic life with long lasting effects.
Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Wear protective gloves. Wear face protection. Wear eye protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. 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. Take any precaution to avoid mixing with combustibles. Avoid breathing vapours.

Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Specific treatment (see information on this label). Rinse mouth. Wash contaminated clothing before reuse. IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. IF ON SKIN: Wash with plenty of water. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF INHALED: Remove person to fresh air and keep comfortable for breathing. Take off immediately all contaminated clothing. And wash it before reuse. Store locked up. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents to in accordance with local/regional/national/international regulations. Wear protective clothing.
regulations. Wear protective clothing.
Keep cool. Avoid release to the environment. Collect spillage.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with shower. Avoid breathing spray. Do not breathe vapours. Do not breathe vapours.

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

# 4.1. Use description

## Table 28

# Use # 1 – Disinfection of surfaces in industrial, public and non-medical healthcare areas. – foam application on surfaces

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	Method: Foam application Detailed description: By foaming via a small foaming can with the diluted product

Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: Non-medical healthcare areas With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1500 mL/100 L) at Room Temperature in 5 min contact time. Application rate: 20 mL/m <sup>2</sup> Use other than in HEALTHCARE With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Application rate: 30 mL/m <sup>2</sup> Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.1.1. Use-specific instructions for use

See general directions for use.

#### 4.1.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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 See general directions for use.
- 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

# 4.2. Use description

## Table 29

# Use # 2 – Disinfection of surfaces and agriculture/horticulture equipment by foaming, manually (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by foaming with prior cleaning
Application method(s)	Method: Foam application Detailed description: By foaming via a small foaming can with the diluted product Foaming is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup> Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.2.1. Use-specific instructions for use

See general directions for use.

4.2.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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 See general directions for use.
- 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

## 4.3. Use description

#### Table 30

# Use # 3 – Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by automatic foaming with prior cleaning
Application method(s)	Method: Foam application
	Detailed description:
	The diluted product is foamed on the equipment in an automated way while the user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device).

	Foaming is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.3.1. Use-specific instructions for use

See general directions for use.

#### 4.3.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

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

See general directions for use.

4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

# 4.4. Use description

## Table 31

# Use # 4 – Disinfection of surfaces and agriculture/horticulture equipment by automatic foaming (closed rooms) (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by automatic foaming with prior cleaning
Application method(s)	Method: Foam application Detailed description: The diluted product is foamed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.4.1. Use-specific instructions for use

See general directions for use.

## 4.4.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

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

See general directions for use.

4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

## 4.5. Use description

#### Table 32

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	Method: Foam application Detailed description: The diluted product is automatically foamed in all directions on the surfaces/walls, via a foaming device. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)

## Use # 5 - Disinfection of animal houses by foaming - foaming with personal enclosure

Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 2 % i.e. 2 000 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

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

It has to be assured that animals are not present when treatment takes place.

4.5.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading and of a factor of 10 during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.5.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

# 4.6. Use description

Table 33

## Use # 6 – Disinfection of animal houses by foaming – foaming without personal enclosure

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	Method: Foam application Detailed description: The diluted product is automatically foamed on the surfaces/walls, in all directions, via a foaming device.
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 2 % i.e. 2 000 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

# 4.6.1. Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

# 4.6.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

EN

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

- 4.6.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.6.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.7. Use description

Table 34

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage: Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces by foaming with prior cleaning

Use # 7 – Disinfection of surfaces by foaming – foaming with personal enclosure

Application method(s)	Method: Foam application
	Detailed description:
	The diluted product is automatically foamed on the surfaces/walls, in all directions, via a foaming device.
	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): Against bacteria & yeasts: With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages): With 0,064 % PAA (Dilution of the product at 2 % i.e. 2 000 mL/100 L) at Room Temperature in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.7.1. Use-specific instructions for use

See general directions for use.

# 4.7.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Respiratory protection with an APF of 10 is required during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.7.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.8. Use description

#### Table 35

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor Indoor – In food industry: Disinfection of hard/non-porous surfaces by foaming with prior cleaning
Application method(s)	Method: Foam application
	Detailed description:
	The diluted product is automatically foamed on the surfaces/walls, in all directions, via a foaming device.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
. /	Dilution (%): Against bacteria & yeasts: With 0,048 % PAA (Dilution of the product at 1.5 % i.e. 1 500 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Against bacteria (including bacterial spores), yeasts and viruses (including bacteriophages): With 0,064 % PAA (Dilution of the product at 2 % i.e. 2 000 mL/100 L) at Room Temperature in 60 min contact time.

Use # 8 – Disinfection of surfaces by foaming – without personal enclosure

	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.8.1. Use-specific instructions for use

See general directions for use.

#### 4.8.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

- 4.8.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 5. GENERAL DIRECTIONS FOR USE (3) OF THE META SPC 3

#### 5.1. **Instructions for use**

1. All the surfaces to be disinfected must be cleaned before the disinfection procedure

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

2. Disinfection cycle:

EN

- Products must be diluted in potable water before use.
- Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
- Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are
  rinsed with water and the water is drained into the sewer system. For exceptions, please refer to the
  description of application method related to each use.

#### Meta SPC 3: Disinfection procedures by foaming

Only for use in areas that are inaccessible to the general public and companion animals.

No access for the general public during treatment.

The surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

#### 5.2. Risk mitigation measures

Dermal protection:

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

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

#### Indirect effects

The two products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.

Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to selfaccelerated, exothermic decomposition and the formation of oxygen.

In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

First aid measures

#### Ø General advice

Move out of dangerous area.

Take care of your own personal safety.

Take off immediately all contaminated clothing.

#### Ø Inhalation

Take affected persons out into the fresh air.

Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.

If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

#### Ø Skin contact

After contact with skin, wash immediately with plenty of water.

Consult a physician.

Take off immediately all contaminated clothing.

Immediately rinse contaminated or saturated clothing with water.

#### Ø Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Protect unharmed eye.

Continue rinsing process with eye rinsing solution.

Call ambulance (caustic burn of the eyes)

Immediate further treatment in ophthalmic hospital/ophthalmologist.

Continue rinsing eye until arrival at ophthalmic hospital.

#### Ø Ingestion

Do not induce vomiting.

Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.

Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.

Notify ambulance immediately (key word: acid burn).

#### Ø Notes to physician

Therapy as for chemical burn.

Following inhalation:

Formation of a toxic lung oedema is possible if product continues to be inhaled despite acute irritative effect (e.g. if it is not possible to leave the danger area).

Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).

If substance has been swallowed:

Aspiration hazard.

Risk of gaseous embolisms.

In case of excessive strain on the stomach due to gas evolution, insert siphon tube.

Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.

If necessary, suck away leftover substance.

Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

Emergency measures to protect the environment

Observe regulations on prevention of water pollution (collect, dam up, cover up).

Do not allow to run into water channels, surface water or into the ground.

#### Ø Methods for cleaning up

Clean contaminated surface thoroughly; recommended cleaning agent is water.

In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemi-sorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

#### Ø Additional advice

Make safe or remove all sources of ignition.

Isolate defective containers immediately, if possible and safe to do.

Shut off leak, if possible and safe to do.

Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).

Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).

Product taken out should not be returned into container.

Never return spilled product into its original container for re-use (risk of decomposition).

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

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place Keep products away from direct sunlight, source of heat and ignition

The shelf life of the biocidal product is 6 months.

The products must be stored at temperatures below + 30 °C.

#### 6. OTHER INFORMATION

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment:

**PAA**: AECinhal =  $0.5 \text{ mg/m}^3$ 

**HP**: AECinhal =  $1,25 \text{ mg/m}^3$ 

#### 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)	ACIDOFOAM CF		Marke	Market area: EU			
	HyPro Biocide 3.2-23a		Marke	larket area: EU			
	TECHMA OXI PB Ma		Marke	et area: EU			
Authorisation number	EU-0026179-0004 1-3						
Common name	IUPAC name	Function		CAS number	EC number	Content (%)	
Peracetic acid		Active Substance		79-21-0	201-186-8	3,2	
Sulphuric acid		Non-active substance		7664-93-9	231-639-5	0,8	
Hydrogen peroxide		Non-active substance		7722-84-1	231-765-0	23,5	
Acetic acid		Non-active substance		64-19-7	200-580-7	6,1	

## **META SPC 4**

1. META SPC 4 ADMINISTRATIVE INFORMATION

#### 1.1. Meta SPC 4 identifier

Identifier	Meta SPC4
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#### Suffix to the authorisation number 1.2.

Number 1-4	
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#### 1.3. Product type(s)

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Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT03 - Veterinary hygiene (Disinfectants) PT04 - Food and feed area (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
Peracetic acid		Active Substance	79-21-0	201-186-8	15,0	15,0
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,78	0,78
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	22,0	22,0
Acetic acid		Non-active substance	64-19-7	200-580-7	16,7	16,7

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

Formulation(s)	SL - Soluble concentrate
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#### 3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Harmful if swallowed. Harmful if inhaled. Causes severe skin burns and eye damage. Causes serious eye damage. May cause respiratory irritation.	Hazard statements	Causes severe skin burns and eye damage. Causes serious eye damage.
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	Very toxic to aquatic life with long lasting effects. Flammable liquid and vapour. Toxic in contact with skin.
Precautionary statements	<ul> <li>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.</li> <li>No smoking.</li> <li>Wear protective gloves.</li> <li>Wear face protection.</li> <li>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.</li> <li>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</li> <li>Immediately call a POISON CENTER/doctor.</li> <li>Take any precaution to avoid mixing with combustibles.</li> <li>Avoid breathing vapours.</li> <li>Wash hands thoroughly after handling.</li> <li>Do not eat, drink or smoke when using this product.</li> <li>Use only outdoors or in a well-ventilated area.</li> <li>Specific treatment (see information on this label).</li> <li>Rinse mouth.</li> <li>Wash contaminated clothing before reuse.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.</li> <li>IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.</li> <li>IF INHALED: Remove person to fresh air and keep comfortable for breathing.</li> <li>Take off immediately all contaminated clothing. And wash it before reuse.</li> <li>Store in a well-ventilated place. Keep container tightly closed.</li> <li>Dispose of contents to local/regional/national/international regulations.</li> <li>Wear protective clothing.</li> <li>Dispose of container to local/regional/national/international regulations.</li> <li>Keep cool.</li> <li>Avoid release to the environment.</li> <li>Collect spillage.</li> <li>IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with shower.</li> <li>Do not breatthe spray.</li> <li>Avoid breathing spray.</li> <li>Do not breatthe vapours.</li> </ul>

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

## 4.1. Use description

Table 36

# Use # 1 – Disinfection of surfaces in industrial, public and non-medical healthcare areas. - manual treatment (mopping)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In Industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by manual treatment (mopping) with prior cleaning
Application method(s)	Method: Manual treatment (mopping).
	Detailed description:
	Diluted product is applied by mopping with the appropriate tool (e.g. flat mops or cleaning cloths).
	After application, the diluted product is drained.
Application rate(s) and frequency	Application Rate: -
nequency	Dilution (%): Against bacteria and yeasts: Non-medical healthcare areas With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) at Room Temperature in 5 min contact time. Application rate: 20 mL/m <sup>2</sup> . Use other than in HEALTHCARE With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Application rate: 30 mL/m <sup>2</sup> .
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
matrial	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.1.1. Use-specific instructions for use

Items to be disinfected by mopping have to stay sufficiently wet during the required contact time to allow optimal disinfection.

#### 4.1.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

Re-entry is only permitted once the air concentrations of peracetic acid and hydrogen peroxide have dropped below the respective reference values (AEC). After the application, the room must be ventilated, preferably by mechanical ventilation. The duration of the ventilation period has to be established by measurement with suitable measurement equipment (specified by authorization holder).

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.2. Use description

#### Table 37

Use # 2 – Disinfection	of surfaces in	1 industrial,	public and	non-medical	healthcare	areas	- manual
		treatmen	t (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	Not relevant
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In Industrial, public and non-medical healthcare areas: Disinfection of hard/non-porous surfaces by manual treatment (spraying) with prior cleaning
Application method(s)	Method: Manual treatment (spraying)
	Detailed description: Diluted product is applied by spraying using a small spraying can.
Application rate(s) and frequency	Application Rate: -
1 /	Dilution (%): Against bacteria and yeasts: Non-medical healthcare areas With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) at Room Temperature in 5 min contact time. Application rate: 20 mL/m <sup>2</sup> . Use other than in

	HEALTHCARE With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature. Application rate: 30 mL/m <sup>2</sup> . Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.2.1. Use-specific instructions for use

See general directions for use.

4.2.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

## 4.3. Use description

Table 38

## Use # 3 - Clean in Place (CIP) in the pharmaceutical and cosmetic industry

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)	Common name: Bacteria Development stage:	
	Common name: Yeasts Development stage:	
Field(s) of use	Indoor In pharmaceutical and cosmetic industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning	
Application method(s)	Method: By CIP procedure	
	Detailed description:	
	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations. After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.	
Application rate(s) and	Application Rate: -	
frequency	Dilution (%): Against bacteria & yeasts: With 0,032 % PAA (Dilution of the product at 0.2133 % i.e.213.33 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature	
	Number and timing of application: /	
Category(ies) of users	Industrial Professional	
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.	

## 4.3.1. Use-specific instructions for use

See general directions for use.

4.3.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Rinse the pump and disconnect it from the installation before maintenance.

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 See general directions for use.
- 4.3.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.4. Use description

Table 39

## Use # 4 – Surface disinfection in greenhouses via spraying by user with personal enclosure (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In greenhouses: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Open system: spray treatment Detailed description: Diluted product is automatically applied in all directions by spraying via a spraying device The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup> Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 60 min contact time. Number and timing of application:

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.4.1. Use-specific instructions for use

See general directions for use.

4.4.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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 See general directions for use.
- 4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.
- 4.5. Use description

#### Table 40

# Use # 5 – Surface disinfection in greenhouses via spraying by user without personal enclosure (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In greenhouses: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Open system: spray treatment
	Detailed description:
	Diluted product is automatically applied in all directions by spraying via a spraying device.
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

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

See general directions for use.

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

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.6. Use description

Table 41

Use # 6 – Disinfection of agriculture & horticulture equipment by soaking (in absence of plants - for
general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning
Application method(s)	Method: Open system: immersion Detailed description: The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 60 min contact time. Number and timing of application:

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.6.1. Use-specific instructions for use

See general directions for use.

#### 4.6.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

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

See general directions for use.

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

See general directions for use.

4.6.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.7. Use description

#### Table 42

# Use # 7 – Disinfection of surfaces and agriculture/horticulture equipment by spraying (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Open system: spray treatment
	Detailed description:
	The diluted product is manually sprayed on the surfaces/equipment using spraying equipment. Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
matrial	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.7.1. Use-specific instructions for use

See general directions for use.

#### 4.7.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance

"The treated surface should not be allowed to dry prior to rinsing".

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

See general directions for use.

- 4.7.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.7.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.8. Use description

#### Table 43

# Use # 8 – Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (in absence of plants - for general hygiene purpose only)

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	Not relevant
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying Detailed description: Diluted product is applied by spraying in an automated way Spraying is only applied downwards and in a horizontal direction.
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Pack sizes and packaging material HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

4.8.1. Use-specific instructions for use

See general directions for use.

4.8.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

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

See general directions for use.

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

See general directions for use.

4.8.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.9. Use description

#### Table 44

# Use # 9 – Disinfection of surfaces and agriculture/horticulture equipment by automatic spraying (closed room) (in absence of plants - for general hygiene purpose only)

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)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:
Field(s) of use	Indoor In agriculture/horticulture areas: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning

Application method(s)	Method: By spraying.
	Detailed description:
	Diluted product is applied by spraying in an automated way without any operator being present
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.9.1. Use-specific instructions for use

See general directions for use.

#### 4.9.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

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

See general directions for use.

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

See general directions for use.

4.9.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.10. Use description

#### Table 45

#### Use # 10 – Disinfection of animal housing via low-pressure spraying by user with personal enclosure

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Spraying Detailed description: Diluted product is automatically applied in all directions by low-pressure manual spraying via a spraying device. The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Application Rate: Between 20 and 300 mL/m <sup>2</sup> Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 0.42 % i.e. 426.6 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.10.1. Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

4.10.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

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

See general directions for use.

4.10.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.11. Use description

Table 46

# Use # 11 – Disinfection of animal housing via low-pressure manual spraying by user without personal enclosure

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor In animal housing: Disinfection of hard/non-porous surfaces by spraying with prior cleaning

Application method(s)	Method: Open system: spray treatment
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure automatic spraying via a spraying device.
Application rate(s) and frequency	Application Rate: Between 20 and 300 mL/m <sup>2</sup>
	Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 0.42 % i.e.426.6 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.11.1. Use-specific instructions for use

It has to be assured that animals are not present when treatment takes place.

#### 4.11.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Only treatment of empty animal housings. Re-entry of animals only after adequate ventilation and when surfaces are dried.

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

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

See general directions for use.

- 4.11.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.11.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage See general directions for use.

#### 4.12. Use description

#### Table 47

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor in animal housing/husbandries: Disinfection of boots by dipping (not for walk-through) with prior cleaning.
Application method(s)	Method: Dipping Detailed description: Diluted product is put in the footbath No rinse needed
Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 0.42 % i.e. 426.6 mL/100 L) in 60 min contact time. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### Use # 12 – Disinfection of boots in footbaths in animal houses/husbandries

See general directions for use.

<sup>4.12.1.</sup> Use-specific instructions for use

4.12.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.12.3. 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.

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

See general directions for use.

4.12.5. 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.

#### 4.13. Use description

Table 48

#### Use # 13 - Disinfection of equipment by dipping

Product type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Viruses Development stage:
Field(s) of use	Indoor Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning

Application method(s)	Method: Soaking.
	Detailed description:
	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and	Application Rate: -
frequency	Dilution (%): Against bacteria, yeasts and viruses: With 0,064 % PAA (Dilution of the product at 0.42 % i.e. 426.6 mL/100 L) in 60 min contact time.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.13.1. Use-specific instructions for use

See general directions for use.

#### 4.13.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance.

4.13.3. 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.

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

See general directions for use.

4.13.5. 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.

#### 4.14. Use description

#### Table 49

# Use # 14 – Disinfection in Aseptic Filling Lines (crown corks, cheese moulds and food crates) - Automated spraying closed systems

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and frequency	Application Rate: -
	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e.426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
Category(ies) of users	Industrial Professional

Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.14.1. Use-specific instructions for use

See general directions for use.

4.14.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

4.14.3. 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.

- 4.14.4. Where specific to the use, the instructions for safe disposal of the product and its packaging See general directions for use.
- 4.14.5. 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.

#### 4.15. Use description

#### Table 50

#### Use # 15 – Disinfection of equipment in the food and beverage industry by immersion

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:

	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces/equipment (small parts such as equipment, spare parts, tools, valves, hoses,) by immersion in soaking baths with prior cleaning
Application method(s)	Method: Soaking.
	Detailed description:
	The concentrated product is pumped in a soaking bath and diluted to the desired use concentration, before immersion of items to be disinfected
Application rate(s) and frequency	Application Rate: - Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e.426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

## 4.15.1. Use-specific instructions for use

See general directions for use.

## 4.15.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

EN

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the application phase.

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during the postapplication phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.15.3. 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.

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

See general directions for use.

- 4.15.5. 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.
- 4.16. Use description

Table 51

# Use # 16 – Disinfection of heat and ion exchangers, membrane filters and glass and PET bottles – CIP procedures

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage: Common name: Bacteriophages Development stage:

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EN

Field(s) of use	Indoor In food and beverage industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Method: Closed systemDetailed description:Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations.After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	Application Rate: - Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e.426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.16.1. Use-specific instructions for use

See general directions for use.

#### 4.16.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Rinse the pump and disconnect it from the installation before maintenance"

4.16.3. 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.

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

See general directions for use.

4.16.5. 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.

#### 4.17. Use description

Table 52

# Use # 17 – Disinfection of surfaces and equipment by low pressure spraying – spraying with personal enclosure

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device
	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device)
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e. 426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.

	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

#### 4.17.1. Use-specific instructions for use

See general directions for use.

#### 4.17.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading and the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

The application should only take place with the user in a personal enclosure and no other person is present.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.17.3. 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.

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

See general directions for use.

4.17.5. 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.

## 4.18. Use description

Table 53

## Use # 18 – Disinfection of surfaces and equipment by low pressure spraying – spraying without personal enclosure

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	Diluted product is automatically applied in all directions by low-pressure spraying via a spraying device.
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e. 426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature Solutional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

4.18.1. Use-specific instructions for use

EN

See general directions for use.

4.18.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 40 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.18.3. 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.

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

See general directions for use.

4.18.5. 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.

#### 4.19. Use description

Table 54

# Product type PT04 - Food and feed area (Disinfectants) Where relevant, an exact description of the authorised use . Target organism(s) (including development stage) Common name: Bacteria Development stage: Common name: Yeasts Development stage: Common name: Bacterial spores Development stage: Common name: Bacterial spores Development stage: Common name: Viruses Development stage:

#### Use # 19 - Disinfection of surfaces and equipment by low pressure spraying, manually

	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by low-pressure spraying with prior cleaning
Application method(s)	Method: Manual application - spraying.
	Detailed description:
	Diluted product is manually applied by low-pressure spraying, only downwards and horizontal.
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup> Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e. 426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 Lbottles, bulk delivery.

#### 4.19.1. Use-specific instructions for use

See general directions for use.

#### 4.19.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing, loading & application phase.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

Use of respiratory protective equipment (RPE) providing a protection factor of 20 is mandatory during the application phase.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.19.3. 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.

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

See general directions for use.

4.19.5. 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.

# 4.20. Use description

Table 55

Product type	PT04 - Food and feed area (Disinfectants)			
Where relevant, an exact description of the authorised use				
Target organism(s) (including development stage)	Common name: Bacteria Development stage:			
	Common name: Yeasts Development stage:			
	Common name: Bacterial spores Development stage:			
	Common name: Viruses Development stage:			
	Common name: Bacteriophages Development stage:			
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by low-pressure spraying with prior cleaning			
Application method(s)	Method: Spraying			
	Detailed description:			
	The diluted product is sprayed on the equipment			

# Use # 20 – Disinfection of surfaces and equipment by low pressure spraying, automatically

	The user is present, seated in a personal enclosure/in a closed cabin (ex. tractor equipped with a spraying/foaming device). Spraying is only applied downwards and in a horizontal direction.		
Application rate(s) and frequency	Application Rate: Between 20 and 200 mL/m <sup>2</sup> Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e. 426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature. Number and timing of application:		
Category(ies) of users	Industrial Professional		
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.		

#### 4.20.1. Use-specific instructions for use

See general directions for use.

#### 4.20.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

RPE are not mandatory during the application phase, on the condition that the user remains in the control room and do not enter the treated area.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

The application is automatic and should only take place when no one is present in the treated area.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.20.3. 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.

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

See general directions for use.

- 4.20.5. 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.
- 4.21. Use description

# Table 56

# Use # 21 – Disinfection of surfaces and equipment by low pressure spraying – automatic spraying (closed room)

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces/equipment by low-pressure spraying with prior cleaning
Application method(s)	Method: Spraying
	Detailed description:
	The diluted solution is sprayed on the surfaces in an automated way without any user being present.
Application rate(s) and	Application Rate: Between 20 and 200 mL/m <sup>2</sup>
frequency	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e.320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e.426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

# 4.21.1. Use-specific instructions for use

See general directions for use.

4.21.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 10 is mandatory during mixing and loading.

RPE are not mandatory during the application phase, on the condition that the user remains in the control room and do not enter the treated area.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

"The treated surface should not be allowed to dry prior to rinsing".

Re-entry of the general public only when surfaces are dried and after sufficient ventilation.

4.21.3. 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.

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

See general directions for use.

4.21.5. 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.

### 4.22. Use description

Table 57

#### Use # 22 – Disinfection of inner surfaces (pipelines, tanks, vessels, ...) by CIP

Product type	PT04 - Food and feed area (Disinfectants)			
Where relevant, an exact description of the authorised use				

Target organism(s) (including development stage)	Common name: Bacteria Development stage:
	Common name: Yeasts Development stage:
	Common name: Bacterial spores Development stage:
	Common name: Viruses Development stage:
	Common name: Bacteriophages Development stage:
Field(s) of use	Indoor In food industry: Disinfection of hard/non-porous surfaces by CIP procedures (with circulation) with prior cleaning
Application method(s)	Method: Closed system
	Detailed description:
	Diluted product does automatically circulate from the CIP holding tanks through closed pipework and installations.
	After the disinfection procedure, the vessels (pipework and tanks) are drained and rinsed with water under closed system conditions.
Application rate(s) and frequency	Application Rate: -
1 2	Dilution (%): - Against bacteria and yeasts: With 0,048 % PAA (Dilution of the product at 0.32 % i.e. 320 mL/100 L) in 15 min contact time, efficient use temperature from + 4 °C up to Room Temperature - Against bacteria (including bacterial spores) and yeasts: With 0,064 % PAA (Dilution of the product at 0.42 % i. e. 426.6 mL/100 L) in 60 min contact time, efficient use temperature from + 4 °C up to Room Temperature For additional activity against viruses (including bacteriophages): the product should be used at Room Temperature.
	Number and timing of application: /
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product):
	Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.

# 4.22.1. Use-specific instructions for use

See general directions for use.

4.22.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

Rinse the pump and disconnect it from the installation before maintenance"

4.22.3. 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.

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

See general directions for use.

4.22.5. 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.

# 4.23. Use description

Table 58

Product type	PT04 - Food and feed area (Disinfectants)			
Where relevant, an exact description of the authorised use				
Target organism(s) (including development stage)	Common name: Bacteria Development stage: Common name: Yeasts Development stage:			
Field(s) of use	Indoor In food industry: Disinfection of water (in clean conditions) used for rinsing of recycled items = Water from drinking water quality shortly stored in tanks until use to rinse items such as bottles. The water should be disinfected to avoid recontamination and in an extent to avoid cross-contamination of inner bottle surfaces			
Application method(s)	Method: Closed system Detailed description: Concentrated product will be pumped into a reservoir from which it is continuously dosed into the water stream. Dilution of the product to the intended in-use concentration occurs in the water stream. This application is a closed, automated process.			

# Use # 23 - Disinfection of water used for rinsing of recycled items during the washing process

Application rate(s) and frequency	Application Rate: - Dilution (%): Against bacteria and yeasts: With 0.008 % PAA (Dilution of the product at 0.0533 % i.e. 53.3 mL/100L) at Room Temperature in 15 min contact			
	time. Number and timing of application: /			
Category(ies) of users	Industrial Professional			
Pack sizes and packaging material	HDPE with screw and venting caps (weight depends on density of product): Jerry cans (10 to 25 kg), Drums (200 to 250 kg), IBC (1 000 to 1 200 kg), 1 L bottles, bulk delivery.			

#### 4.23.1. Use-specific instructions for use

See general directions for use.

4.23.2. Use-specific risk mitigation measures

Dermal protection:

Use appropriate safety glasses and/or face shield during the mixing & loading.

Respiratory protection:

Use of respiratory protective equipment (RPE) providing a protection factor of 4 is mandatory during mixing and loading.

When the product is being used in areas accessible to the public, mark treated areas during the treatment period and indicate possible risks for humans and non-target organisms (e.g. primary and secondary poisoning) as well as first measures to be taken in case of poisoning.

Rinse the pump and disconnect it from the installation before maintenance"

4.23.3. 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.

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

See general directions for use.

- 4.23.5. 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 (4) OF THE META SPC 4

# 5.1. **Instructions for use**

- 1. All the surfaces to be disinfected must be cleaned before the disinfection procedure.
- (\*) 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.

1. Disinfection cycle:

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- Products must be diluted in potable water before use.
- Dilution rate & contact time depends on the use considered. Please refer to the description of application method related to each use.
- Final rinsing (with potable water) is mandatory: after the disinfection procedure, treated surfaces are rinsed with water and the water is drained into the sewer system. For exceptions, please refer to the description of application method related to each use.

Only for use in areas that are inaccessible to the general public and companion animals.

No access for the general public during treatment.

Disinfection procedures by CIP: Final rinsing step (with potable water).

After the disinfection procedure, CIP vessels (pipework and tanks) are drained and rinsed with water under closed system conditions

Disinfection procedures **by dipping**: The bath is not intended to be re-used. Use the bath only once a day after work & replace it by a fresh solution daily.

Disinfection procedures **by spraying:** the surfaces to be disinfected must be wet enough in order to keep them wet during the required contact time for optimal disinfection. Then, the user should pay attention to wet surfaces completely with the disinfectant solution.

The Application Rate for spraying of diluted product must be between 20 and 30 mL/m<sup>2</sup>

## 5.2. Risk mitigation measures

#### Dermal protection:

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

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

#### Indirect effects

The two products are oxidising agents and reactive. In case of thermal decomposition steam and oxygen will be released as decomposition products. The release of oxygen may support combustion.

Also, contact with impurities, decomposition catalysts, metallic salts, alkalis, reducing agents may lead to self-accelerated, exothermic decomposition and the formation of oxygen.

In case of decomposition of the products in confined spaces and pipers, there is a risk of overpressure and burst.

First aid measures

#### Ø General advice

Move out of dangerous area.

Take care of your own personal safety.

Take off immediately all contaminated clothing.

## Ø Inhalation

Take affected persons out into the fresh air.

Possible discomfort: Irritates skin and mucous linings of the eyes and respiratory tract and cough.

If breathing difficulties occur (e.g. severe continual coughing): Keep patient half sitting with upper body raised; keep warm and in a quiet place; call a physician immediately.

# Ø Skin contact

After contact with skin, wash immediately with plenty of water.

Consult a physician.

Take off immediately all contaminated clothing.

Immediately rinse contaminated or saturated clothing with water.

### Ø Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Protect unharmed eye.

Continue rinsing process with eye rinsing solution.

Call ambulance (caustic burn of the eyes)

Immediate further treatment in ophthalmic hospital/ophthalmologist.

Continue rinsing eye until arrival at ophthalmic hospital.

#### Ø Ingestion

Do not induce vomiting.

Danger of penetration of the lungs (danger to breathing) when swallowed or vomited, due to gas evolution and foam formation.

Only when patient fully conscious: have the mouth rinsed with water; have the patient drink plenty of water in small sips; keep patient warm and at rest.

Notify ambulance immediately (key word: acid burn).

#### Ø Notes to physician

Therapy as for chemical burn.

Following inhalation:

Formation of a toxic lung oedema is possible if product continues to be inhaled despite acute irritative effect (e.g. if it is not possible to leave the danger area).

Prophylaxis of a toxic lung oedema with inhalative steroids (dosing spray, e.g. auxilosone).

If substance has been swallowed:

Aspiration hazard.

Risk of gaseous embolisms.

In case of excessive strain on the stomach due to gas evolution, insert siphon tube.

Early endoscopy in order to assess mucosa lesions in the oesophagus and stomach which may appear.

If necessary, suck away leftover substance.

Do not administer activated charcoal, since risk of release of large amounts of gas from hydrogen peroxide.

Emergency measures to protect the environment

Observe regulations on prevention of water pollution (collect, dam up, cover up).

Do not allow to run into water channels, surface water or into the ground.

# Ø Methods for cleaning up

Clean contaminated surface thoroughly; recommended cleaning agent is water.

In case of small spills, dilute product with lots of water and rinse away or absorb product with liquid-binding material, e.g. chemi-sorption, diatomaceous earth, universal binder. Do not use textiles, saw dust, combustible substances. After binding, pick up mechanically and collect in suitable containers. Dispose of absorbed material in accordance with the regulations.

#### Ø Additional advice

Make safe or remove all sources of ignition.

Isolate defective containers immediately, if possible and safe to do.

Shut off leak, if possible and safe to do.

Place defective containers in waste receptacle (waste packaging receptacle) made of plastic (not metal).

Do not seal defective containers or waste receptacles airtight (danger of bursting due to product decomposition).

Product taken out should not be returned into container.

Never return spilled product into its original container for re-use (risk of decomposition).

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

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains

Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place. Keep products away from direct sunlight, source of heat and ignition

The shelf life of the biocidal product is 6 months.

The products must be stored at Ambient Temperature.

#### 6. OTHER INFORMATION

Reference values of peracetic acid and hydrogen peroxide used for the risk assessment:

**PAA**: AECinhal =  $0.5 \text{ mg/m}^3$ 

**HP**: AECinhal =  $1,25 \text{ mg/m}^3$ 

# 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)	SOPUROXID 15	Market area: EU	
	HORTICLEAN 15 FORT	Market area: EU	
	AGRIOXID 15	Market area: EU	
	HyPro Biocide 15-22	Market area: EU	
Authorisation number	EU-0026179-0005 1-4		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	15,0
Sulphuric acid		Non-active substance	7664-93-9	231-639-5	0,78
Hydrogen peroxide		Non-active substance	7722-84-1	231-765-0	22,0
Acetic acid		Non-active substance	64-19-7	200-580-7	16,7

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

Trade name(s)	Oxypur CS		Marke	arket area: EU			
Authorisation number	EU-0026179-0	EU-0026179-0006 1-4					
Common name	IUPAC name	Function		CAS number	EC number	Content (%)	
Peracetic acid		Active Substance		79-21-0	201-186-8	15,0	
Sulphuric acid		Non-active substance		7664-93-9	231-639-5	0,78	
Hydrogen peroxide		Non-active substance		7722-84-1	231-765-0	22,0	
Acetic acid		Non-active substance		64-19-7	200-580-7	16,7	

## COMMISSION IMPLEMENTING REGULATION (EU) 2022/965

#### of 21 June 2022

# authorising the placing on the market of kernels from the edible variety of Jatropha curcas L. as a novel food and amending 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 (<sup>1</sup>), and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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 (<sup>2</sup>) has established a Union list of novel foods.
- (3) On 29 August 2016, the company 'JatroSolutions GmbH' ('the applicant') submitted an application to the competent authority of Germany to place kernels from the edible variety of *Jatropha curcas* L., on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council (<sup>3</sup>). The applicant requested for hydrothermally treated whole and broken kernels from the edible variety of *Jatropha curcas* L. to be used as such (or candied or sugar preserved) or as processed nuts as snack, and as a food ingredient in cereal bars, in breakfast cereals, and in dried fruits.
- (4) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 are to be treated as an application submitted under Regulation (EU) 2015/2283.
- (5) While the request for placing kernels from the edible variety of *Jatropha curcas* L. on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (6) On 1 March 2018, the applicant also made a request to the Commission for the protection of proprietary data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers (<sup>4</sup>), the compositional data including the nutritional information (<sup>5</sup>) and data on allergens (<sup>6</sup>), the information on biological and process contaminants (<sup>7</sup>), the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels (<sup>8</sup>), the procedures for the verification of the phorbol ester content of the *Jatropha*

<sup>(&</sup>lt;sup>1</sup>) OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> 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).

<sup>(&</sup>lt;sup>3</sup>) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

<sup>(4)</sup> JatroSolutions GmbH (2018 and 2019, unpublished)

<sup>(5)</sup> JatroSolutions GmbH (2021, unpublished)

<sup>(&</sup>lt;sup>6</sup>) JatroSolutions GmbH (2020 and 2021, unpublished)

<sup>(7)</sup> JatroSolutions GmbH (2021, unpublished)

<sup>(8)</sup> JatroSolutions GmbH (2021, unpublished)

*curcas* L. kernels (?), bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil (<sup>10</sup>), and an *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil (<sup>11</sup>), submitted in support of the application.

- (7) On 19 October 2018, the Commission requested the European Food Safety Authority ('the Authority') to carry out an assessment of kernels from the edible variety of *Jatropha curcas* L. as a novel food.
- (8) On 24 November 2021, the Authority adopted its scientific opinion 'Safety of hydrothermally treated kernels from edible Jatropha curcas L. ('Chuta') as a novel food pursuant to Regulation (EU) 2015/2283 (<sup>12</sup>) in accordance with Article 11 of Regulation (EU) 2015/2283.
- (9) In its scientific opinion, the Authority concluded that kernels from the edible variety of *Jatropha curcas* L. are safe under the proposed conditions of use. Therefore, that scientific opinion gives sufficient grounds to establish that novel food kernels from the edible variety of *Jatropha curcas* L., when used as such (or candied or sugar preserved) or as processed nuts as snack and as a food ingredient in cereal bars, in breakfast cereals, and in dried fruits, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (10) In its scientific opinion, the Authority also concluded that consumption of this novel food may either induce primary sensitisation to kernels from the edible variety of *Jatropha curcas* L. that could lead to allergic reactions or could elicit allergic reactions to persons that are allergic to nuts. It came to such conclusion on the basis of the weight of the available evidence and considering the elevated (32 %) protein content of the kernels from the edible variety of *Jatropha curcas* L., and published information demonstrating the presence of a number of allergenic proteins in the kernels from the non-edible variety of *Jatropha curcas* L.. However, considering that at present there is no epidemiological evidence on allergic reactions to kernels from the edible variety of *Jatropha curcas* L. in the areas of Mexico where they are commonly consumed, and considering the negative cross reactivity results of proteins from the kernels from the edible variety of *Jatropha curcas* L. to proteins from some common nuts in *in vitro* enzymelinked immunosorbent assays ('ELISA'), and the negative polymerase chain reaction ('PCR') tests conducted with the kernels from the edible variety of *Jatropha curcas* L. for allergens of other nuts, the Commission considers that no specific labelling requirement as to its allergenicity should be included in the Union list of authorised novel foods.
- (11) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on the scientific data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, and the *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, without which it could not have assessed the novel food and reached its conclusion.
- (12) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those studies and tests and to clarify its claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (13) The applicant declared that they held proprietary and exclusive rights of reference to the scientific data from the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the sampling procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal

<sup>(9)</sup> JatroSolutions GmbH (2021, unpublished)

<sup>(&</sup>lt;sup>10</sup>) JatroSolutions GmbH (2021, unpublished)

<sup>(&</sup>lt;sup>11</sup>) JatroSolutions GmbH (2021, unpublished)

<sup>(&</sup>lt;sup>12</sup>) EFSA Journal 2022; 20(1):6998.

and oil, and the *in vitro* mammalian cell micronucleus tests with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, at the time they submitted the application and therefore third parties could not lawfully access, use or refer to those data.

- (14) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific data on the management of the cultivation of the *Jatropha curcas* L. plant and the use of molecular markers, the compositional data including the nutritional information and data on allergens, the information on biological and process contaminants, the analytical methods, including their validation, for the detection of phorbol esters in the *Jatropha curcas* L. kernels, the procedures for the verification of the phorbol ester content of the *Jatropha curcas* L. kernels, the bacterial reverse mutation assays with the edible and non-edible *Jatropha curcas* L. defatted kernel meal and oil, should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place kernels from *Jatropha curcas* L. on the market within the Union during a period of 5 years from the entry into force of this Regulation.
- (15) However, restricting the authorisation of kernels from the edible variety of *Jatropha curcas* L. and the reference to the scientific data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.
- (16) 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. Kernels from the edible variety of *Jatropha curcas* L. are authorised to be placed on the market within the Union.

Kernels from the edible variety of *Jatropha curcas* L. shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

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

#### Article 2

Only the company JatroSolutions GmbH' (<sup>13</sup>) is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of 5 years from 12 July 2022, unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of JatroSolutions GmbH'.

#### Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of 5 years from 12 July 2022 without the agreement of 'JatroSolutions GmbH'.

#### Article 4

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

<sup>(&</sup>lt;sup>13</sup>) Address: Echterdinger Strasse 30, 70599 Stuttgart, Germany.

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

Done at Brussels, 21 June 2022.

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 th	ne novel food may be used	Additional specific labelling requirements	Other requirements	Data Protection
Jatropha curcas L.	Specified food category	Maximum levels (g/100g)			Authorised on 12 July 2022. This inclusion is based
(edible variety) kernels	Kernels as such, candied or sugar preserved and as processed nuts		food on the labelling of the foodstuffs containing it shall be "kernels from edible <i>Jatropha</i> <i>curcas</i> L."		on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: "JatroSolutions GmbH", Echterdinger
	Cereal bars	5			Strasse 30, 70599 Stuttgart, Germany. During the period of data protection, the novel food kernels
	Breakfast cereals	5			from the edible variety of Jatropha curcas L. is
	Dried fruits	5			authorised for placing on the market within the Union only by "JatroSolutions GmbH", unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of "JatroSolution GmbH". End date of the data protection: 12 July 2027.'

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

Authorised Novel Food	Specification	
kernels , , , , , , , , , , , , , , , , , , ,	<b>Description:</b> The kernels are obtained from the seeds of the ripe fruits of the edible variety of the <i>Jatropha curcas</i> L. plants that produce kernels with non- detectable levels of phorbol esters, following a series of steps involving the cleaning and de-husking of the fruits to obtain the seeds, the drying of the seeds, the cleaning of the seeds to remove debris and other residues, mechanical deshelling of the seeds to obtain the kernels, and the hydrothermal treatment (> 120 °C for 40 minutes) of the kernels to reduce anti-nutrients and the microbiological load. As the edible variety of the <i>Jatropha curcas</i> L. plants, producing kernels that contain non-detectable levels of phorbol esters, are phenotypically undistinguishable from the non-edible variety, only the appropriate edible variety of <i>Jatropha curcas</i> L. plants should be used in the production of the novel food. The entire production process must ensure that the mixing of edible and non-edible kernels does not occur.	

The absence of mixing of edible with non-edible kernels shall be confirmed by analytical controls for phorbol esters carried on each batch of the seeds after the seed-drying step and before the deshelling step according to the sampling procedure of Table A. Five laboratory samples extracted from each aggregate sample are de-shelled, ground, and analysed for phorbol esters using a validated UHPLC-UV-MS<sup>(b)</sup> method. Only the batches in which phorbol esters are undetectable in all five samples are further processed to the seed deshelling and kernel hydrothermal treatment steps.

Batch weight (tons)	Weight or number of sublots	Number of incremental samples
≥ 500	100 tons	100
> 100 and < 500	5 sub-lots	100
> 10 and ≤ 100	5 sub-lots	100
> 5,0 and ≤ 10	-	80
> 1 and ≤ 5,0	-	60
> 0,1 and ≤ 1,0	-	30
≤ 0,1	-	10

Each sub-lot shall be sampled separately. Aggregate samples are composed by a minimum of 10 incremental samples. The minimum amount of an aggregate sample shall be 3,5 kg. This amount may increase proportionally according to the number of incremental samples taken.

# Characteristics/Composition:

Moisture: ≤ 3,0 %

Total fat: 54,0 – 61,0 %

Total protein: 21,0 - 32,0 %

Total fibre: 6,0 – 10,0 %

Ash: 3,0 – 5,0 %

# Contaminants:

Phorbol esters ( $\mu g$  TPA eq<sup>(a)</sup>/g kernel)<sup>(b)</sup>:  $\leq 0,75$  (LOD)<sup>(c)</sup>

Lead:  $\leq$  0,20 mg/kg

Cadmium:  $\leq 0,20$  mg/kg

Sum of aflatoxins B1, B2, G1, G2:  $\leq$  4,0 µg/kg

# Microbiological criteria:

Total aerobic microbial count:  $\leq 1\ 000\ \text{CFU}/\text{g}$ 

Total yeast/moulds count:  $\leq$  100 CFU/g

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Enterobacteriaceae: ≤ 10 CFU/g Salmonella sp.: Absent in 25 g Listeria monocytogenes: ≤ 100 CFU/g
<sup>(a)</sup> TPAeq: 12-O-tetradecanoylphorbol-13-acetate equivalent; <sup>(b)</sup> Validated Ultra-High-Performance Liquid Chromatography coupled to Ultraviolet Spectrophotometry and Mass Spectrometry (UHPLC-UV-MS) method for detection of phorbol ester peaks; <sup>(c)</sup> Limit of Detection (Only batches with concentrations of PEs below the LOD can be fully processed.); CFU: Colony Forming Units'

# COMMISSION IMPLEMENTING REGULATION (EU) 2022/966

#### of 21 June 2022

amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use, the specific labelling requirements and specifications of the novel food *Calanus finmarchicus* oil

(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 (<sup>1</sup>), and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods 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 (<sup>2</sup>) has established a Union list of novel foods.
- (3) The Union list set out in the Annex to Implementing Regulation (EU) 2017/2470 includes *Calanus finmarchicus* oil as an authorised novel food.
- (4) Commission Implementing Decision (EU) 2017/2353 (<sup>3</sup>) authorised, in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council (<sup>4</sup>), the placing on the market of *Calanus finmarchicus* oil as a novel food ingredient to be used in food supplements intended for the general population.
- (5) On 30 November 2021, the company 'Calanus A/S' ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 for a change of the specifications, of the conditions of use, and of the specific labelling requirements of the novel food '*Calanus finmarchicus* oil'. The applicant proposed to change the specifications of *Calanus finmarchicus* oil with regard to astaxanthin esters to the level up to 0,25 %. They requested an increased maximum level of up to 0,25 % of astaxanthin esters contained in *Calanus finmarchicus* oil for persons older than fourteen years of age, in addition to the currently authorised maximum level of < 0,1 % of astaxanthin esters in *Calanus finmarchicus* oil for the general population. For food supplements containing the currently authorised level of < 0,1 % astaxanthin esters that are intended for the general population, the applicant proposed reducing the currently authorised use levels of the *Calanus finmarchicus* oil from 2,3 g/day to 1,0 g/day and excluding infants and young children.
- (6) As a consequence of the proposed changes in the specifications *Calanus finmarchicus* oil and the conditions of use of this novel food, the applicant proposed an amendment in its labelling to ensure that consumers only use the food supplements intended for their age group. In addition, in light of the current use of food supplements containing astaxanthin esters in the Union market, the applicant also proposed additional specific labelling to warn consumers not to use *Calanus finmarchicus* oil food supplements, when other food supplements containing astaxanthin esters are consumed on the same day.

<sup>(1)</sup> OJ L 327, 11.12.2015, p. 1.

<sup>(2)</sup> 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).

<sup>(&</sup>lt;sup>3</sup>) Commission Implementing Decision (EU) 2017/2353 of 14 December 2017 authorising the placing on the market of oil from *Calanus finmarchicus* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 336, 16.12.2017, p. 45).

<sup>(\*)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (7) The Commission considers that the requested update of the Union list concerning specifications of *Calanus finmarchicus* oil and the resulting changes in its conditions of use for the population groups older than 14 years of age is not liable to have an effect on human health and that a safety evaluation by the European Food Safety Authority ('the Authority') in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The increase in the astaxanthin esters in oil from *Calanus finmarchicus* from < 0,1 % to  $\leq$  0,25 % in food supplements intended for population groups older than 14 years is expected to result in intakes of astaxanthin esters which, in combination with the intake of astaxanthin from the normal diet, are not expected to exceed the revised Acceptable Daily Intake ('ADI') of 0,2 mg astaxanthin/kg bw, established by the Authority (').
- (8) Furthermore, the Commission considers that the requested update of the Union list concerning the reduction of the currently authorised use levels of *Calanus finmarchicus* oil from 2,3 g/day to 1,0 g/day in food supplements intended for the general population that contain < 0,1 % astaxanthin esters, and the exclusion of infants and young children is also not liable to have an effect on human health and that a safety evaluation by the Authority in accordance with Article 10(3) of Regulation (EU) 2015/2283 is not necessary. The exclusion of infants and young children is justified because the anticipated combined intake of astaxanthin esters from food supplements containing *Calanus finmarchicus* oil with levels of < 0,1 % astaxanthin esters and from the normal diet is expected to exceed the revised Acceptable Daily Intake ('ADI') of 0,2 mg astaxanthin/kg of body weight established by the Authority for these groups of consumers.
- (9) The proposed change to the specifications and conditions of use of *Calanus finmarchicus* oil as regards the astaxanthin esters values are in line with the conclusions of the safety assessment conducted by the Authority on astaxanthin. Therefore, it is appropriate to amend the specifications and the conditions of use of the novel food *Calanus finmarchicus* oil at the proposed astaxanthin esters levels.
- (10) The proposed changes to the labelling requirements of *Calanus finmarchicus* oil are in line with the conclusions of the safety assessment conducted by the Authority on astaxanthin. In addition, the Commission considers appropriate to lay down additional labelling requirement in order to prevent concomitant consumption of astaxanthin food supplements, which is likely to exceed the ADI established by the Authority. Therefore, it is appropriate to include additional labelling requirements for that novel food.
- (11) The information provided in the application gives sufficient grounds to establish that the changes to the conditions of use, the specific labelling requirements and specifications of the novel food *Calanus finmarchicus* oil are in accordance with the conditions of Article 12 of Regulation (EU) 2015/2283 and should be approved.
- (12) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (13) In order to provide business operators with sufficient time to adjust their practices to comply with the requirements of this Regulation, transitional measures should be laid down as regards food supplements containing *Calanus finmarchicus* oil, which have been lawfully placed on the Union market or dispatched from third countries for the Union, before the date of entry into force of this Regulation.
- (14) 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

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

<sup>(&</sup>lt;sup>5</sup>) Safety of astaxanthin for its use as a novel food in food supplements; EFSA Journal 2020;18(2):5993.

### Article 2

1. *Calanus finmarchicus* oil food supplements which were lawfully placed on the market before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

2. *Calanus finmarchicus* oil food supplements which were dispatched from a third country and were on their way to the Union before the date of entry into force of this Regulation and complying with the rules in force before the date of entry into force of this Regulation, may be marketed until their date of minimum durability or use by date.

#### 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.

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

Done at Brussels, 21 June 2022.

For the Commission The President Ursula VON DER LEYEN

22.6.2022

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

(1) in Table 1 (Authorised novel foods), the entry for '*Calanus finmarchicus* oil' is replaced by the following:

Authorised novel food	Conditions under which	the novel food may be used	Additional specific labelling requirements	Other requirements
Calanus finmarchicus oil	Specified food category	Maximum levels	1. The designation of the novel food on	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	for the general population, excluding infants and young children 2,3 g/day (from 0,1 % to $\leq$ 0,25 % astaxanthin esters, resulting in $\leq$ 5,75 mg astaxanthin per day) for the general population older than 14 years of age	<ol> <li>The labelling of food supplements containing <i>Calanus finmarchicus oil</i> shall bear a statement that those food</li> </ol>	

(2) in Table 2 (Specifications), the entry for 'Calanus finmarchicus oil' is replaced by the following:

Authorised Novel Food	Specifications	
'Calanus finmarchicus oil	Description/Definition:         The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton)         Calanus finmarchicus. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids.         Specifications:         Water: < 1,0 %	

Docosahexaenoic acid (DHA): > 4,0 % Total fatty alcohols: > 28 % C20:1 n-9 fatty alcohol: > 9,0 % C22:1 n-11 fatty alcohol: > 12 %	22.6.2022
Trans fatty acids: < 1,0 % Astaxanthin esters: ≤ 0,25 % Peroxide value (PV): < 3,0 meq. O <sub>2</sub> /kg'	EN

# DECISIONS

### COUNCIL DECISION (EU) 2022/967

# of 13 June 2022

on the position to be taken on behalf of the European Union within the Association Council established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, as regards the adoption of the EU-Republic of Moldova Association Agenda

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part (<sup>1</sup>) ('the Agreement') was signed on 27 June 2014 and entered into force on 1 July 2016.
- (2) Pursuant to Article 436(1) of the Agreement, the Association Council has the power to adopt recommendations, for the purposes of attaining the objectives of the Agreement.
- (3) To facilitate the application of the Agreement, the Parties have agreed to establish an association agenda with a view to providing a list of priorities for their joint work on a sector-by-sector basis.
- (4) The Association Council is to adopt the recommendation on the EU-Republic of Moldova Association Agenda for 2021-2027 by written procedure.
- (5) It is appropriate to establish the position to be taken on the Union's behalf in the Association Council, as the EU-Republic of Moldova Association Agenda for 2021-2027 will be the basis for programming under the Neighbourhood, Development and International Cooperation Instrument.
- (6) The position of the Union within the Association Council on the adoption of the EU-Republic of Moldova Association Agenda for 2021-2027 should therefore be based on the draft recommendation of the Association Council,

HAS ADOPTED THIS DECISION:

# Article 1

The position to be taken on the Union's behalf within the Association Council established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, as regards the adoption of the EU-Republic of Moldova Association Agenda for 2021-2027 shall be based on the draft recommendation of the Association Council attached to this Decision.

<sup>(1)</sup> OJ L 260, 30.8.2014, p. 4.

# Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 13 June 2022.

For the Council The President M. FESNEAU

# DRAFT

# RECOMMENDATION No ../2022 OF THE EU-REPUBLIC OF MOLDOVA ASSOCIATION COUNCIL

#### of ...

#### on the EU-Republic of Moldova Association Agenda

THE EU-REPUBLIC OF MOLDOVA ASSOCIATION COUNCIL,

Having regard to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part (<sup>1</sup>) ('the Agreement') was signed on 27 June 2014 and entered into force on 1 July 2016.
- (2) In accordance with Article 436(1) of the Agreement, the Association Council has the power to adopt recommendations, for the purposes of attaining the objectives of the Agreement.
- (3) Pursuant to Article 453(1) of the Agreement, the Parties are to take any general or specific measures required to fulfil their obligations under the Agreement and are to ensure that the objectives set out in the Agreement are attained.
- (4) Article 11 of the Rules of Procedure of the Association Council provides for the possibility of taking decisions by written procedure between sessions if both Parties so agree.
- (5) The Union and the Republic of Moldova have agreed to consolidate their partnership by agreeing on a set of priorities for the period 2021–2027 for the joint work towards achieving the objectives of political association and economic integration as set out in the Agreement.
- (6) The Parties to the Agreement have agreed on the text of the EU-Republic of Moldova Association Agenda for 2021–2027, which will support the implementation of the Agreement, focusing cooperation on commonly identified shared interests,

HAS ADOPTED THE FOLLOWING RECOMMENDATION:

#### Article 1

The Association Council recommends that the Parties implement the EU-Republic of Moldova Association Agenda, as set out in the Annex (\*).

#### Article 2

The EU-Republic of Moldova Association Agenda, as set out in the Annex, shall replace the EU-Republic of Moldova Association Agenda which was adopted on 19 August 2017.

#### Article 3

This Recommendation shall take effect on the date of its adoption.

<sup>&</sup>lt;sup>(1)</sup> OJ EU L 260, 30.8.2014, p. 4.

<sup>(\*)</sup> See document ST 6701/22 ADD 2 at https://register.consilium.europa.eu.

Done at ...,

For the Association Council The Chair

# COUNCIL DECISION (EU) 2022/968

# of 16 June 2022

# appointing two members of the Court of Auditors

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 286(2) thereof,

Having regard to the proposals by the Republic of Cyprus and Malta,

Having regard to the opinions of the European Parliament (1),

Whereas:

(1) The term of office of Mr Leo BRINCAT is due to expire on 30 September 2022.

(2) The term of office of Mr Lazaros LAZAROU is due to expire on 1 November 2022.

(3) Two members should therefore be appointed to the Court of Auditors,

HAS ADOPTED THIS DECISION:

#### Article 1

The following are hereby appointed members of the Court of Auditors:

- Mr Lefteris CHRISTOFOROU, for the period from 2 November 2022 to 1 November 2028,
- Mr George Marius HYZLER, for the period from 1 October 2022 to 30 September 2028.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 16 June 2022.

For the Council The President O. DUSSOPT

<sup>(1)</sup> Opinions of 3 May 2022 (not yet published in the Official Journal).

#### COUNCIL DECISION (EU) 2022/969

#### of 16 June 2022

on the position to be taken on behalf of the European Union in the World Forum for Harmonization of Vehicle Regulations of the United Nations Economic Commission for Europe as regards the proposals for modifications to UN Regulations Nos 12, 13, 13-H, 22, 24, 48, 49, 51, 53, 54, 74, 79, 85, 86, 90, 100, 106, 109, 117, 127, 129, 131, 135, 136, 137, 141, 145, 148, 149, 150, 157 and 162, as regards the proposal for modifications to UN GTR No 2, as regards the proposal for a new UN Regulation on reverse warning, as regards the proposal for a new UN Global Technical Regulation on durability of pollution control devices for two- and three-wheelers, as regards the proposal for a new Consolidated Resolution concerning exhaust ultra-fine particle numbers measurement for heavy duty vehicles, and as regards the proposal for authorisation to develop Amendment 4 to UN GTR No 3

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) By Council Decision 97/836/EC (<sup>1</sup>), the Union acceded to the Agreement of the United Nations Economic Commission for Europe (UNECE) concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement'). The Revised 1958 Agreement entered into force on 24 March 1998.
- (2) By Council Decision 2000/125/EC (<sup>2</sup>), the Union acceded to the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement'). The Parallel Agreement entered into force on 15 February 2000.
- (3) Regulation (EU) 2018/858 of the European Parliament and of the Council (<sup>3</sup>) lays down administrative provisions and technical requirements for type approval and placing on the market of all new vehicles, systems, components and separate technical units. This Regulation incorporates regulations adopted under the Revised 1958 Agreement ('UN Regulations') in the EU type approval system, either as requirements for type approval or as alternatives to Union legislation.
- (4) Pursuant to Article 1 of the Revised 1958 Agreement and Article 6 of the Parallel Agreement, the UNECE World Forum for Harmonization of Vehicle Regulations ('UNECE WP.29') may adopt proposals for modifications to UN Regulations, UN Global Technical Regulations ('UN GTRs') and UN Resolutions, as well as proposals for new UN Regulations, UN GTRs and UN Resolutions concerning the approval of vehicles. Moreover, pursuant to those provisions, UNECE WP.29 may adopt proposals for authorisations to develop amendments to UN GTRs or to develop new UN GTRs and may adopt proposals for the extension of mandates for UN GTRs.

<sup>(&</sup>lt;sup>1</sup>) Council Decision 97/836/EC of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement') (OJ L 346, 17.12.1997, p. 78).

<sup>(&</sup>lt;sup>2</sup>) Council Decision 2000/125/EC of 31 January 2000 concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement') (OJ L 35, 10.2.2000, p. 12).

<sup>(&</sup>lt;sup>3</sup>) Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).

- (5) At the 187th session of the World Forum to be held between 21 and 24 June 2022, UNECE WP.29 intends to adopt the proposals for modifications to UN Regulations Nos 12, 13, 13-H, 22, 24, 48, 49, 51, 53, 54, 74, 79, 85, 86, 90, 100, 106, 109, 117, 127, 129, 131, 135, 136, 137, 141, 145, 148, 149, 150, 157 and 162; the proposal for modifications to UN GTR No 2; the proposal for a new UN Regulation on reverse warning; the proposal for a new UN GTR on durability of pollution control devices for two- and three-wheelers; and the proposal for a new Consolidated Resolution concerning exhaust ultra-fine particle numbers measurement for heavy duty vehicles. Moreover, UNECE WP.29 intends to adopt the proposal for authorisation to develop Amendment 4 to UN GTR No 3 on motorcycle braking.
- (6) It is appropriate to establish the position to be taken on the Union's behalf in UNECE WP.29, as regards the adoption of those proposals, as the UN Regulations will be binding on the Union and, together with the UN GTRs and UN Resolutions, capable of decisively influencing the content of Union law in the field of vehicle type approval.
- (7) In the light of experience and technical developments, the requirements relating to certain elements or features covered by UN Regulations Nos 12, 13, 13-H, 22, 24, 48, 49, 51, 53, 54, 74, 79, 85, 86, 90, 100, 106, 109, 117, 127, 129, 131, 135, 136, 137, 141, 145, 148, 149, 150, 157, 162 and UN GTR No 2 need to be amended or supplemented.
- (8) In order to allow for technical progress and in order to improve vehicle safety and reduce environmental footprint, a new UN Regulation on reverse warning, a new UN GTR on durability of pollution control devices for two- and threewheelers and a new Consolidated Resolution concerning exhaust ultra-fine particle numbers measurement for heavy duty vehicles need to be adopted,

HAS ADOPTED THIS DECISION:

# Article 1

The position to be taken on behalf of the European Union in the 187th session of the UNECE World Forum for Harmonization of Vehicle Regulations to be held between 21 and 24 June 2022 shall be to vote in favour of the proposals listed in the Annex to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 16 June 2022.

For the Council The President O. DUSSOPT

# Regulation No Agenda item title Document reference (1) 12 Proposal for the 05 series of amendments to UN Regulation No 12 ECE/TRANS/WP.29/2022/69 (Steering mechanism) ECE/TRANS/WP.29/GRSP/70, para. 8, based on ECE/TRANS/WP.29/ GRSP/2021/18, as amended by Annex II to the report 13 Proposal for a Supplement 19 to the 11 series of amendments to UN ECE/TRANS/WP.29/2022/77 Regulation No 13 (Heavy vehicle braking) ECE/TRANS/WP.29/GRVA/12, para. 82, based on ECE/TRANS/WP.29/ GRVA/2022/9 13 ECE/TRANS/WP.29/2022/78 Proposal for a Supplement 1 to the 12 series of amendments to UN Regulation No 13 (Heavy vehicle braking) ECE/TRANS/WP.29/GRVA/12, para. 82, based on ECE/TRANS/WP.29/ GRVA/2022/9 13-H ECE/TRANS/WP.29/2022/79 Proposal for a Supplement 4 to UN Regulation No 13-H (Braking of light vehicles) ECE/TRANS/WP.29/GRVA/12, para. 83, based on ECE/TRANS/WP.29/ GRVA/2022/10, as amended by GRVA-12-24 22 ECE/TRANS/WP.29/2022/63 Proposal for Supplement 2 to the 06 series of amendments to UN Regulation No 22 (Protective helmets) ECE/TRANS/WP.29/GRSP/70, para. 16, based on ECE/TRANS/WP.29/ GRSP/2021/24 as amended by Annex III to the report 24 Proposal for Supplement 8 to the 03 series of amendments to UN ECE/TRANS/WP.29/2022/73 Regulation No 24 (Visible pollutants, measurement of power of C.I. engines (Diesel smoke)) ECE/TRANS/WP.29/GRPE/85, para. 35, based on ECE/TRANS/WP.29/ GRPE/2022/4 48 Proposal for Supplement 16 to the 06 series of amendments to UN ECE/TRANS/WP.29/2022/89 Regulation No 48 (Installation of lighting and light-signalling devices) ECE/TRANS/WP.29/GRE/85, paras. 17, 31 and 33, based on ECE/ TRANS/WP.29/GRE/2021/16 as amended by GRE-85-23, ECE/TRANS/ WP.29/GRE/2021/18 as amended by GRE-85-33 and ECE/TRANS/ WP.29/GRE/2020/5/Rev.2 as amended by GRE-85-26 48 Proposal for Supplement 3 to the 07 series of amendments to UN ECE/TRANS/WP.29/2022/90 Regulation No 48 (Installation of lighting and light-signalling devices) ECE/TRANS/WP.29/GRE/85, para. 17, 31 and 33, based on ECE/ TRANS/WP.29/GRE/2021/16 as amended by GRE-85-23, ECE/TRANS/ WP.29/GRE/2021/18 as amended by GRE-85-33 and ECE/TRANS/ WP.29/GRE/2020/5/Rev.2, as amended by GRE-85-26

# ANNEX

Regulation No	Agenda item title	Document reference (1)
48	Proposal for Supplement 1 to the 08 series of amendments to UN Regulation No 48 (Installation of lighting and light-signalling devices)	ECE/TRANS/WP.29/2022/91
	ECE/TRANS/WP.29/GRE/85, para. 17, 31 and 33, based on ECE/ TRANS/WP.29/GRE/2021/16 as amended by GRE-85-23, ECE/TRANS/ WP.29/GRE/2021/18 as amended by GRE-85-33 and ECE/TRANS/ WP.29/GRE/2020/5/Rev.2 as amended by GRE-85-26	
48	Proposal for Supplement 8 to the 03 series of amendments to UN Regulation No 48 (Installation of lighting and light-signalling devices)	ECE/TRANS/WP.29/2022/95
	ECE/TRANS/WP.29/GRE/85, para. 20, based on ECE/TRANS/WP.29/GRE/2021/17, as amended by GRE-85-12 and para. 19 of the report	
48	Proposal for Supplement 21 to the 04 series of amendments to UN Regulation No 48 (Installation of lighting and light-signalling devices)	ECE/TRANS/WP.29/2022/96
	ECE/TRANS/WP.29/GRE/85, para. 20, based on ECE/TRANS/WP.29/ GRE/2021/17, as amended by GRE-85-12 and para. 19 of the report	
48	Proposal for Supplement 16 to the 05 series of amendments to UN Regulation No 48 (Installation of lighting and light-signalling devices)	ECE/TRANS/WP.29/2022/97
	ECE/TRANS/WP.29/GRE/85, para. 20, based on ECE/TRANS/WP.29/GRE/2021/17, as amended by GRE-85-12 and para. 19 of the report	
49	Proposal for Supplement 1 to the 07 series of amendments to UN Regulation No 49 (Emissions of compression ignition and positive ignition (LPG and CNG) engines)	ECE/TRANS/WP.29/2022/74
	ECE/TRANS/WP.29/GRPE/85, para. 29, based on ECE/TRANS/WP.29/ GRPE/2022/3 and GRPE-85-47 as amended by Annex IV	
51	Proposal for Supplement 7 to 03 series of amendments to UN Regulation No 51 (Noise of M and N categories of vehicles)	ECE/TRANS/WP.29/2022/84, WP.29-187-07
	ECE/TRANS/WP.29/GRBP/72 and ECE/TRANS/WP.29/GRBP/73, based on ECE/TRANS/WP.29/GRBP/2021/22 as amended by para. 5 of ECE/ TRANS/WP.29/GRBP/72, ECE/TRANS/WP.29/GRBP/2022/4 as amended by GRBP-75-37, ECE/TRANS/WP.29/GRBP/2022/3 as amended by GRBP-75-36 and para. 4 of ECE/TRANS/WP.29/GRBP/73, ECE/TRANS/WP.29/GRBP/2022/8 as amended by para. 6 of ECE/ TRANS/WP.29/GRBP/73, GRBP-74-40 as amended by para. 9 of ECE/ TRANS/WP.29/GRBP/73	

Regulation No	Agenda item title	Document reference (1)
53	Proposal for Supplement 23 to the 01 series of amendments to UN Regulation No 53 (Installation of lighting and light-signalling devices for L3 vehicles)	ECE/TRANS/WP.29/2022/98
	ECE/TRANS/WP.29/GRE/85, para. 23, and ECE/TRANS/WP.29/GRE/ 83, para. 36, based on ECE/TRANS/WP.29/GRE/2021/19 and ECE/ TRANS/WP.29/GRE/2020/13/Rev.1 as amended by GRE-83-51	
53	Proposal for Supplement 6 to the 02 series of amendments to UN Regulation No 53 (Installation of lighting and light-signalling devices for L3 vehicles)	ECE/TRANS/WP.29/2022/99
	ECE/TRANS/WP.29/GRE/85, para. 24, and ECE/TRANS/WP.29/GRE/ 83, para. 36, based on ECE/TRANS/WP.29/GRE/2021/20 and ECE/ TRANS/WP.29/GRE/2020/13/Rev.1 as amended by GRE-83-51	
53	Proposal for Supplement 3 to the 03 series of amendments to UN Regulation No 53 (Installation of lighting and light-signalling devices for L3 vehicles)	ECE/TRANS/WP.29/2022/100
	ECE/TRANS/WP.29/GRE/85, para. 24, and ECE/TRANS/WP.29/GRE/ 83, para. 36, based on ECE/TRANS/WP.29/GRE/2021/20 and ECE/ TRANS/WP.29/GRE/2020/13/Rev.1 as amended by GRE-83-51	
54	Proposal for Supplement 25 to the original series of amendments to UN Regulation No 54 (Tyres for commercial vehicles and their trailers)	ECE/TRANS/WP.29/2022/85
	ECE/TRANS/WP.29/GRBP/73, based on ECE/TRANS/WP.29/GRBP/ 2022/6 and ECE/TRANS/WP.29/GRBP/2021/13, as amended by GRBP- 75-31-Rev.2	
74	Proposal for Supplement 14 to the 01 series of amendments to UN Regulation No 74 (Installation of lighting and light-signalling devices for mopeds)	ECE/TRANS/WP.29/2022/101
	ECE/TRANS/WP.29/GRE/85, para. 25, based on ECE/TRANS/WP.29/ GRE/2021/21	
74	Proposal for Supplement 2 to the 02 series of amendments to UN Regulation No 74 (Installation of lighting and light-signalling devices for mopeds)	ECE/TRANS/WP.29/2022/102
	ECE/TRANS/WP.29/GRE/85, para. 25, based on ECE/TRANS/WP.29/ GRE/2021/21	
79	Proposal for a Supplement 8 to the 03 series of amendments to UN Regulation No 79 (Steering Equipment)	ECE/TRANS/WP.29/2022/80
	ECE/TRANS/WP.29/GRVA/12, para. 65-66, based on ECE/TRANS/WP.29/GRVA/2022/6, as amended by GRVA-12-43 and ECE/TRANS/WP.29/GRVA/2021/11, as amended by GRVA-12-19	

Regulation No	Agenda item title	Document reference (1)
79	Proposal for a Supplement 3 to the 04 series of amendments to UN Regulation No 79 (Steering Equipment) ECE/TRANS/WP.29/GRVA/12, para. 65-66, based on ECE/TRANS/ WP.29/GRVA/2022/6, as amended by GRVA-12-43 and ECE/TRANS/ WP.29/GRVA/2021/11, as amended by GRVA-12-19	ECE/TRANS/WP.29/2022/81
85	Proposal for Supplement 11 to UN Regulation No 85 (Measurement of the net power and the 30 min. power) ECE/TRANS/WP.29/GRPE/85, para. 37, based on ECE/TRANS/WP.29/GRPE/2022/5 as amended by GRPE-85-11 and during the session as reproduced in Annex V	ECE/TRANS/WP.29/2022/75
86	Proposal for Supplement 4 to the 01 series of amendments to UN Regulation No 86 (Installation of lighting and light-signalling devices for agricultural vehicles) ECE/TRANS/WP.29/GRE/85, para. 26, based on ECE/TRANS/WP.29/ GRE/2021/22	ECE/TRANS/WP.29/2022/103
86	Proposal for Supplement 1 to the 02 series of amendments to UN Regulation No 86 (Installation of lighting and light-signalling devices for agricultural vehicles) ECE/TRANS/WP.29/GRE/85, para. 26, based on ECE/TRANS/WP.29/ GRE/2021/22	ECE/TRANS/WP.29/2022/104
90	Proposal for a Supplement 9 to the 02 series of amendments to UN Regulation No 90 (Replacement braking parts) ECE/TRANS/WP.29/GRVA/12, para. 90, based on ECE/TRANS/WP.29/ GRVA/2021/29, as amended by GRVA-12-16	ECE/TRANS/WP.29/2022/82
100	Proposal for Supplement 2 to the 03 series to UN Regulation No 100 (Electric power trained vehicles) ECE/TRANS/WP.29/GRSP/70, para. 17, based on GRSP-70-26 as reproduced by Annex IV to the report	ECE/TRANS/WP.29/2022/64
106	Proposal for Supplement 20 to the original series of amendments to UN Regulation No 106 (Tyres for agricultural vehicles and their trailers) ECE/TRANS/WP.29/GRBP/73, based on ECE/TRANS/WP.29/GRBP/ 2022/7	ECE/TRANS/WP.29/2022/86
109	Proposal for Supplement 11 to UN Regulation No 109 (Retreaded tyres for commercial vehicles and their trailers) Revision 1 ECE/TRANS/WP.29/GRBP/72, paras. 18 and 19, based on ECE/TRANS/ WP.29/GRBP/2021/18 and ECE/TRANS/WP.29/GRBP/2021/16 as amended by Annex IV to the report and informal document WP.29-186-07	ECE/TRANS/WP.29/2022/7/ Rev.1

Regulation No	Agenda item title	Document reference (1)
117	Proposal for a new 03 series of amendments to UN Regulation No 117 (Tyre rolling resistance, rolling noise and wet grip) ECE/TRANS/WP.29/GRBP/72, para. 23 and ECE/TRANS/WP.29/GRBP/ 73, based on GRBP-74-33-Rev.1, ECE/TRANS/WP.29/GRBP/2021/17 as amended by GRBP-74-31-Rev.1 and GRBP-75- 25-Rev.1	ECE/TRANS/WP.29/2022/83
127	Proposal for the 03 series of amendments to UN Regulation No 127 (Pedestrian safety) ECE/TRANS/WP.29/GRSP/70, para. 18, based on ECE/TRANS/WP.29/ GRSP/2021/28 as amended by Annex V to the report	ECE/TRANS/WP.29/2022/70
129	Proposal for Supplement 7 to the 03 series of amendments to UN Regulation No 129 (Enhanced Child Restraint systems) ECE/TRANS/WP.29/GRSP/70, para. 20, based on ECE/TRANS/WP.29/ GRSP/2021/7 as amended by Annex VI to the report	ECE/TRANS/WP.29/2022/65
131	Proposal for the 02 series of amendments to UN Regulation No 131 (Advanced Emergency Braking System) ECE/TRANS/WP.29/GRVA/12, para. 72, based on ECE/TRANS/WP.29/ GRVA/2022/7, as amended by GRVA-12-49 (reproduced in GRVA- 12-50/Rev.1)	ECE/TRANS/WP.29/2022/76
135	Proposal for the 02 series of amendments to UN Regulation No 135 (Pole side impact) ECE/TRANS/WP.29/GRSP/70, para. 23, based on ECE/TRANS/WP.29/ GRSP/2021/21 not amended	ECE/TRANS/WP.29/2022/71
136	Proposal for the 01 series of amendments to UN Regulation No 136 (Electric vehicle L) ECE/TRANS/WP.29/GRSP/70, para. 24, based on ECE/TRANS/WP.29/ GRSP/2021/22, as amended by Annex VII to the report	ECE/TRANS/WP.29/2022/72
137	Proposal for Supplement 4 to the 01 series of amendments to UN Regulation No 137 (Frontal impact with focus on restraint systems) ECE/TRANS/WP.29/GRSP/70, para. 26, based on ECE/TRANS/WP.29/ GRSP/2021/23, not amended	ECE/TRANS/WP.29/2022/66
137	Proposal for Supplement 3 to the 02 series of amendments to UN Regulation No 137 (Frontal impact with focus on restraint systems) ECE/TRANS/WP.29/GRSP/70, para. 26, based on ECE/TRANS/WP.29/ GRSP/2021/23, not amended	ECE/TRANS/WP.29/2022/67

Regulation No	Agenda item title	Document reference (1)
141	Proposal for Supplement 2 to the 01 series of amendments to UN Regulation No 141 (Tyre pressure monitoring system)	ECE/TRANS/WP.29/2022/87
	ECE/TRANS/WP.29/GRBP/73, based on ECE/TRANS/WP.29/GRBP/ 2022/2 as amended by GRBP-75-10 and GRBP-75-33	
145	Proposal for Supplement 2 to the original version to UN Regulation No 145 (ISOFIX anchorage systems, ISOFIX top tether anchorages and i-Size)	ECE/TRANS/WP.29/2022/68
	ECE/TRANS/WP.29/GRSP/70, para. 27, based on ECE/TRANS/WP.29/GRSP/2021/27 not amended	
148	Proposal for the 01 series of amendments to UN Regulation No 148 (Light signalling devices)	ECE/TRANS/WP.29/2022/92
	ECE/TRANS/WP.29/GRE/85, paras. 9 and 33, based on ECE/TRANS/WP.29/GRE/2021/13, as amended by GRE-85-09 and GRE-85-13, and ECE/TRANS/WP.29/GRE/2020/5/Rev.2, as amended by GRE-85-26	
149	Proposal for the 01 series of amendments to UN Regulation No 149 (Road illumination devices)	ECE/TRANS/WP.29/2022/93,
	ECE/TRANS/WP.29/GRE/85, paras. 12 and 31, and ECE/TRANS/WP.29/GRE/83, para. 36, based on ECE/TRANS/WP.29/GRE/2021/14 as amended by GRE-85-09 and GRE-85-14, ECE/TRANS/WP.29/GRE/2021/18, as amended by GRE-85-33 and ECE/TRANS/WP.29/GRE/2020/13/Rev.1 as amended by GRE-83-51	WP.29-187-05
150	Proposal for the 01 series of amendments to UN Regulation No 150 (Retro-reflective devices)	ECE/TRANS/WP.29/2022/94
	ECE/TRANS/WP.29/GRE/85, para. 15, based ECE/TRANS/WP.29/GRE/2021/15, as amended by GRE-85-15	
157	Proposal for the 01 series of amendments to UN Regulation No 157 (Automated Lane Keeping Systems)	ECE/TRANS/WP.29/2022/59/ Rev.1
	ECE/TRANS/WP.29/GRVA/12, para. 30, based on ECE/TRANS/WP.29/ GRVA/2022/3, ECE/TRANS/WP.29/GRVA/2022/4, both amended by GRVA-12-52	
	GRVA-13-49e	
162	Proposal for Supplement 2 to the original series of amendments to UN Regulation No 162 (Immobilizers)	ECE/TRANS/WP.29/2022/110
	ECE/TRANS/WP.29/GRSG/102, based on GRSG-123-04	
New Regulation	Proposal for a new UN Regulation on Reverse Warning	ECE/TRANS/WP.29/2022/88
	ECE/TRANS/WP.29/GRBP/73, based on ECE/TRANS/WP.29/GRBP/ 2022/5, as amended by GRBP-75-13	

(1) All documents referred to in the table are available at: (WP.29) World Forum for the Harmonization of Regulations (187th session) | UNECE.

Global Technical Regulation No	Agenda item title	Document reference
2	Proposal for a new Amendment 5 to UN GTR No 2 (Worldwide Motorcycle emissions Test Cycle (WMTC))	ECE/TRANS/WP.29/2022/108
	ECE/TRANS/WP.29/GRPE/85, para. 50, based on ECE/TRANS/WP.29/ GRPE/2022/6 as amended by GRPE-85-38 as reproduced in Addendum 2	

Global Technical Regulation No	Agenda item title	Document reference
	Proposal for a technical report on the development of a new Amendment 5 to UN GTR No 2 (Worldwide Motorcycle emissions Test Cycle (WMTC)) ECE/TRANS/WP.29/GRPE/85, para. 50	ECE/TRANS/WP.29/2022/109
New GTR	Proposal for a new UN GTR on durability of pollution-control devices for two- and three-wheelers ECE/TRANS/WP.29/GRPE/85, para. 52, based on ECE/TRANS/WP.29/ GRPE/2022/7, as amended by GRPE-85-39 as reproduced in Addendum 3	ECE/TRANS/WP.29/2022/106
	Proposal for a technical report on the development of a new UN GTR on durability of pollution-control devices for two- and three-wheelers ECE/TRANS/WP.29/GRPE/85, para. 52	ECE/TRANS/WP.29/2022/107

Miscellaneous	Agenda item title	Document reference
Consolidated Resolution	Proposal for a new Consolidated Resolution concerning Exhaust Ultra- Fine Particle Number Measurement For Heavy Duty Engines	ECE/TRANS/WP.29/2022/105
	ECE/TRANS/WP.29/GRPE/85, para. 46, based on ECE/TRANS/WP.29/GRPE/2021/17, as amended by GRPE-85-04-Rev.1 as reproduced in Addendum 1	
Authorisa- tion	Authorization to develop Amendment 4 to UN GTR No 3 (Motorcycle braking)	ECE/TRANS/WP.29/2022/47/ Rev.1
Guidelines	Proposal for Guidelines and Recommendations concerning Safety Requirements for Automated Driving Systems	ECE/TRANS/WP.29/2022/56
Master document	Proposal for the second iteration of the New Assessment/Test Method for Automated Driving – Master Document	ECE/TRANS/WP.29/2022/57
	ECE/TRANS/WP.29/GRVA/12, para. 24, based on ECE/TRANS/WP.29/ GRVA/2022/2, as amended by GRVA-12-12 and reproduced in WP.29-186-09	
Guidelines	Proposal for the New Assessment/Test Method for Automated Driving (NATM) Guidelines for Validating Automated Driving System GRVA-13-35	ECE/TRANS/WP.29/2022/58, WP.29-187-08
	GRVA-13-35	

Miscellaneous	Agenda item title	Document reference
Recommen- dation	Proposal for recommendations on uniform provisions concerning cyber security and software updates	ECE/TRANS/WP.29/2022/60
	ECE/TRANS/WP.29/GRVA/12, para. 47, based on ECE/TRANS/WP.29/ GRVA/2022/5	
Interpreta- tion document	Proposal for amendments to the Interpretation Document ECE/TRANS/ WP.29/2021/59 for UN Regulation No 155 (Cyber security and cyber security management system)	ECE/TRANS/WP.29/2022/61
	ECE/TRANS/WP.29/GRVA/12, para. 46, based on ECE/TRANS/WP.29/ 2021/59, as amended by GRVA-12-37	
Guidelines	Proposal for amendments to the 'specifications and application guidelines for the Unique Identifier (UI) module' document	ECE/TRANS/WP.29/2022/62
	ECE/TRANS/WP.29/2019/77 ECE/TRANS/WP.29/1161, para. 70, based on ECE/TRANS/WP.29/2019/77, as amended by WP.29-185-13	

#### COUNCIL DECISION (EU) 2022/970

#### of 16 June 2022

on the position to be taken on behalf of the European Union within the ACP-EU Committee of Ambassadors as regards the amendment of Decision No 3/2019 of the ACP-EU Committee of Ambassadors to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 217 in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part (<sup>1</sup>) (the 'ACP-EU Partnership Agreement') was signed in Cotonou on 23 June 2000 and entered into force on 1 April 2003. In accordance with Decision No 3/2019 of the ACP-EU Committee of Ambassadors (<sup>2</sup>) (the 'decision on transitional measures'), it is to be applied until 30 June 2022.
- (2) Pursuant to Article 95(4), first subparagraph, of the ACP-EU Partnership Agreement, negotiations towards a new ACP-EU Partnership Agreement (the 'new Agreement') were launched in September 2018. The new Agreement will not be ready to be applied by 30 June 2022, the expiry date of the current legal framework. It is therefore necessary to amend the decision on transitional measures in order to further extend the application of the provisions of the ACP-EU Partnership Agreement.
- (3) Article 95(4), second subparagraph, of the ACP-EU Partnership Agreement provides for the ACP-EU Council of Ministers to adopt any transitional measures that may be required until the new Agreement comes into force.
- (4) Pursuant to Article 15(4) of the ACP-EU Partnership Agreement, on 23 May 2019, the ACP-EU Council of Ministers delegated the powers to adopt the transitional measures to the ACP-EU Committee of Ambassadors (<sup>3</sup>). Therefore it is for the ACP-EU Committee of Ambassadors to amend the transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement.
- (5) It is appropriate to establish the position to be taken on the Union's behalf in the ACP-EU Committee of Ambassadors, as the envisaged act will be binding on the Union.
- (6) The provisions of the ACP-EU Partnership Agreement will continue to be applied with the aim of maintaining continuity in relations between the Union and its Member States, on the one hand, and the ACP States, on the other. Accordingly, the amended transitional measures are not intended as amendments to the ACP-EU Partnership Agreement as provided for in Article 95(3) thereof,

<sup>(&</sup>lt;sup>1</sup>) OJ L 317, 15.12.2000, p. 3. The ACP-EU Partnership Agreement was amended by the Agreement signed in Luxembourg on 25 June 2005 (OJ L 209, 11.8.2005, p. 27) and by the Agreement signed in Ouagadougou on 22 June 2010 (OJ L 287, 4.11.2010, p. 3).

<sup>(&</sup>lt;sup>2</sup>) Decision No 3/2019 of the ACP-EU Committee of Ambassadors of 17 December 2019 to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement (OJ L 1, 3.1.2020, p. 3).

<sup>(&</sup>lt;sup>3</sup>) Decision No 1/2019 of the ACP-EU Council of Ministers of 23 May 2019 on the delegation of powers to the ACP-EU Committee of Ambassadors on the decision to adopt transitional measures pursuant to Article 95(4) of the ACP-EU Partnership Agreement (OJ L 146, 5.6.2019, p. 114).

HAS ADOPTED THIS DECISION:

EN

#### Article 1

1. The position to be taken on the Union's behalf within the ACP-EU Committee of Ambassadors, pursuant to Article 95(4) of the ACP-EU Partnership Agreement, shall be to amend Decision No 3/2019 of the ACP-EU Committee of Ambassadors in order to extend the application of the provisions of the ACP-EU Partnership Agreement until 30 June 2023, or until the entry into force of the new Agreement or the provisional application between the Union and the ACP States of the new Agreement, whichever comes first.

2. The provisions of the ACP-EU Partnership Agreement shall be applied in line with the purpose and objective of Article 95(4) thereof.

#### Article 2

This Decision shall enter into force on the date of its adoption.

Done at Luxembourg, 16 June 2022.

For the Council The President O. DUSSOPT

# **GUIDELINES**

#### GUIDELINE (EU) 2022/971 OF THE EUROPEAN CENTRAL BANK

#### of 19 May 2022

on the Centralised Securities Database and the production of securities issues statistics and repealing Guideline 2012/689/EU (ECB/2012/21) and Guideline (EU) 2021/834 (ECB/2021/15) (ECB/2022/25)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 5.1, 12.1 and 14.3 thereof,

Having regard to Council Regulation (EC) No 2533/98 of 23 November 1998 concerning the collection of statistical information by the European Central Bank (<sup>1</sup>), and in particular Article 4 thereof,

Having regard to the contribution of the General Council of the European Central Bank,

Whereas:

- (1) The Centralised Securities Database (CSDB) is a single information technology infrastructure operated jointly by the members of the European System of Central Banks (ESCB), including national central banks of the Member States whose currency is not the euro (hereinafter 'non-euro area NCBs') where such non-euro area NCBs voluntarily participate in the operation of the CSDB. The CSDB stores item-by-item data, in particular, data on securities, their issuers, prices and ratings. The main processes of the CSDB's operation comprise input data provision, processing of that input data, carrying out data quality management (DQM) and production and dissemination of output data consisting of item-by-item data and aggregate information. A number of changes to these processes require the adoption of a new Guideline to ensure that there are clear and certain arrangements for the governance of the CSDB. In the interest of legal certainty, Guideline 2012/689/EU of the European Central Bank (ECB/2012/21) (<sup>2</sup>) and Guideline (EU) 2021/834 of the European Central Bank (ECB/2021/15) (<sup>3</sup>) , which to date have governed the data quality management framework of the CSDB and the reporting of statistical information on securities issues, should be repealed.
- (2) To enhance monetary policy and financial stability analyses for the euro area and the Union, to contribute to the production of secondary statistics, to fulfil the euro area reporting commitments on debt securities issuance statistics in the context of the G20 Data Gaps Initiative and to assess the role of the euro in international financial markets, monthly securities issues statistics covering stock and flow aggregates of securities issuances are produced from CSDB item-by-item data (hereinafter 'CSEC aggregate statistics'). Accordingly, CSEC aggregate statistics should be compiled in the CSDB, and national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') and the European Central Bank (ECB) should be responsible for the verification of CSEC aggregate statistics and for the DQM of the underlying CSDB item-by-item data.

<sup>&</sup>lt;sup>(1)</sup> OJ L 318, 27.11.1998, p. 8.

<sup>(2)</sup> Guideline 2012/689/EU of the European Central Bank of 26 September 2012 on the data quality management framework for the Centralised Securities Database (ECB/2012/21) (OJ L 307, 7.11.2012, p. 89).

<sup>&</sup>lt;sup>(3)</sup> Guideline (EU) 2021/834 of the European Central Bank of 26 March 2021 on statistical information to be reported on securities issues (ECB/2021/15) (OJ L 208, 11.6.2021, p. 311).

- (3) Providing input data for the CSDB involves collecting data from various sources and transmitting it to the ECB via the CSDB. This collection by the ECB is necessary in order to undertake the tasks of the ESCB, particularly those regarding monetary policy and the stability of the financial system. These sources include the NCBs and the noneuro area NCBs, ECB-internal sources, certain commercial data providers, administrative sources, and the public domain.
- (4) To link the security-by-security data collected from different sources and to avoid duplicate records, all securities that are transmitted to the CSDB should be identified uniquely by an International Securities Identification Number (ISIN code). To ensure the correct grouping of the input data provided by NCBs and accurate linking of the CSDB data with other ESCB statistical information, NCBs should provide, as part of their input reference data on issuers, at least one linking entity identifier that is included in the Register of Institutions and Affiliates Database (RIAD). Furthermore, to facilitate the correct grouping of issuer reference data from different sources and accurate linking with other ESCB statistical information, a Legal Entity Identifier (LEI) should be provided when available.
- (5) The overall quality of CSDB item-by-item data can only be assessed at the output level, rather than at the level of individual sets of input data. To ensure the completeness, accuracy and consistency of output data, it is necessary to define a DQM framework to be applied to output feed data, which is a subset of output data that can be used to support the production of statistics or other uses.
- (6) The CSDB DQM framework should be applied to output feed data regardless of the source of input data. It should lay down the responsibilities of the NCBs and the ECB for the quality of output data in the CSDB. In order to ensure the high quality of output feed data and CSEC aggregate statistics, and to enable the ECB to provide snapshots of output feed data and the CSEC aggregate statistics in a timely manner, NCBs and the ECB should verify output feed data and CSEC aggregate statistics by a specified date.
- (7) To ensure the high quality of CSDB item-by-item data and of historical CSEC aggregate statistics, and to support the alignment of NCBs' national security-by-security databases and the CSDB, NCBs that have improved their input data should provide revised input data files to the CSDB or use the CSDB system to correct the data.
- (8) Since the CSDB is operated jointly by all ESCB members, they should all aim to follow the same DQM standards. Where an NCB would like to conduct DQM that affects the CSDB data related to residents in other countries, it should coordinate with the NCBs and the non-euro area NCBs and with the ECB, as relevant, to clearly define the boundaries of such DQM. Moreover, non-euro area NCBs are in the best position to carry out DQM on the data related to issuers residing in their respective Member States. While it is recognised that guidelines adopted by the ECB may not impose any obligations on non-euro area NCBs, Article 5 of the Statute of the European System of Central Banks and of the European Central Bank applies to both NCBs and non-euro area NCBs. This implies an obligation on non-euro area NCBs to therefore design and implement all the measures that they consider appropriate in order to carry out DQM of CSDB output data and CSEC aggregate statistics in accordance with this Guideline. In addition, for the purposes of enabling the ECB to obtain a comprehensive overview of the statistical information collected and to carry out relevant analyses, the national central banks of non-euro area Member States that adopt the euro should be required to provide the ECB with statistical information covering a specified period prior to their adoption of the euro.
- (9) To improve the quality of output data, data source management (DSM) should be carried out with the aim of identifying and correcting repetitive and/or structural mistakes in input data. DSM should be carried out by the ECB in relation to input data provided by commercial data sources and by NCBs in relation to their own input data.
- (10) Common rules should be established for the publication by NCBs of aggregate statistics using CSDB data to ensure an orderly release of the related key aggregates.
- (11) It is necessary to set up a procedure to carry out technical amendments to the annexes to this Guideline in an effective manner, provided that such amendments neither change the underlying conceptual framework nor affect the reporting and DQM burden,

HAS ADOPTED THIS GUIDELINE:

#### Article 1

#### Definitions

For the purposes of this Guideline the following definitions shall apply:

- (1) 'Centralised Securities Database' or 'CSDB' means the Centralised Securities Database set up by the European System of Central Banks (ESCB);
- (2) 'input data' means any data provided to the CSDB from one or more of the following data sources: a) both national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') and national central banks of the Member States whose currency is not the euro (hereinafter the 'non-euro area NCBs'; b) European Central Bank-internal sources; c) commercial data providers; d) administrative sources; e) the public domain;
- (3) 'input provision bracket' means a period of working days each calendar month, which is defined by the European Central Bank (ECB) and during which the NCBs may provide input data to the CSDB;
- (4) 'output data' means item-by-item data that are automatically derived in the CSDB by compounding input data into complete, high quality single data records;
- (5) 'output feed data' means the subset of item-by-item output data and characteristics listed in Annex III to this Guideline that support the production of statistics or other uses;
- (6) 'CSEC aggregate statistics' means aggregated securities issues statistics covering stock and flow aggregates of securities issuances produced from item-by-item CSDB output data as specified in Annex IV to this Guideline;
- (7) 'Data Quality Management' or 'DQM' means the activity of ensuring, verifying and maintaining the quality of output feed data and CSEC aggregate statistics through the use and application of DQM targets, DQM metrics, DQM thresholds and specific DQM workflows;
- (8) 'Data Source Management' or 'DSM' means the activity of identifying and correcting directly with a data provider repetitive and/or structural mistakes in input data;
- (9) 'initial DQM' means DQM of item-by-item output feed data and CSEC aggregate statistics, covering the end-month preview for the most recent reference month and carried out on a monthly basis;
- (10) 'regular DQM' means DQM of item-by-item output feed data and CSEC aggregate statistics, covering the reference months prior to the month covered by initial DQM and carried out on a monthly basis, taking into account non-CSDB benchmark data provided by various data sources with a view to ensuring that CSDB output data quality satisfies the requirements for CSDB feed data;
- (11) 'DQM target' means a benchmark for assessing the quality of output feed data, as specified in Annex II to this Guideline;
- (12) 'DQM metric' means a statistical indicator measuring the level to which a certain DQM target has been reached, as specified in Annex II to this Guideline;
- (13) 'DQM threshold' means the minimum level of verification work to be conducted in order to satisfy the requirements of the DQM framework for a DQM target;
- (14) 'DQM exception' means a possible data quality issue that is identified via a specified rule and for which the data needs to be confirmed or corrected in order to reach the respective DQM threshold;
- (15) 'DQM workflow' means a technical process applied for the correction of input data in order to comply with a DQM threshold;
- (16) 'end-month preview' means a daily update of output data and of DQM metrics which produces an approximation of output data for the forthcoming end-month status;
- (17) 'initial CSEC aggregate statistics' means CSEC aggregate statistics covering the most recent reference month;
- (18) 'regular CSEC aggregate statistics' means CSEC aggregate statistics covering the reference months prior to the month covered by initial CSEC aggregate statistics;

- (19) 'CSEC priority series' means the lowest-level CSEC aggregate statistics that are subject to the DQM requirements, as specified in Annex II and Annex IV to this Guideline;
- (20) 'reference month' means the calendar month to which the relevant data or statistics refer;
- (21) 'working day' is a complete day which is not an ECB public holiday, as published on the ECB's website;
- (22) 'verification' means the process of checking CSDB output feed data as well as CSEC aggregate statistics and, if necessary, correcting CSDB input data, hereby applying the DQM workflow;
- (23) 'resident' has the meaning defined in Regulation (EU) No 549/2013 of the European Parliament and of the Council (\*);
- (24) 'ISIN code' means the International Securities Identification Number, as defined by the International Standards Organization (ISO) in ISO 6166;
- (25) 'linking entity identifier' means an entity identifier that is included both in the CSDB and in the ESCB's Register of Institutions and Affiliates Data (RIAD) data set and that is either a RIAD code, another national entity identifier used by the relevant NCB or non-euro area NCB, a Legal Entity Identifier (LEI) defined by ISO 17442, or another entity identifier commonly accepted by the ECB and the relevant NCB or non-euro area NCB.

#### Subject matter and scope

This Guideline establishes a framework for the production of securities data and securities issues statistics in the CSDB. The aim of this framework is to ensure the completeness, accuracy and consistency of CSDB output data and CSEC aggregate statistics by consistently applying rules on the provision of input data and DQM and DSM for such data.

#### Article 3

#### Role of the ECB and NCBs

1. The ECB, with the assistance of the NCBs, shall define the CSDB's operational processes; compile the CSEC aggregate statistics; and produce output data, including output feed data.

- 2. In accordance with this Guideline, the NCBs shall:
- (a) provide input data on securities issued by residents in their Member States to the CSDB where they have such data readily available;
- (b) conduct the DQM of the data related to issuers resident in their Member States;
- (c) verify the CSEC aggregate statistics related to issuers resident in their Member States.
- 3. The ECB shall:
- (a) conduct the DQM of data related to issuers resident outside the euro area, unless a non-euro area NCB has accepted the responsibility to conduct DQM for data related to issuers resident in its Member State;
- (b) verify the CSEC aggregate statistics related to issuers resident outside the euro area, unless a non-euro area NCB has accepted the responsibility for verifying the CSEC aggregate statistics related to issuers resident in its Member State.

<sup>(4)</sup> Regulation (EU) No 549/2013 of the European Parliament and of the Council of 21 May 2013 on the European system of national and regional accounts in the European Union (OJ L 174, 26.6.2013, p. 1).

#### Article 4

#### Provision of input data by NCBs

1. Where NCBs have readily available item-by-item data on securities issued by residents in their Member States, they shall provide these data to the CSDB on a regular basis.

2. Where NCBs have readily available item-by-item data on securities issued by residents of other countries, they may provide these data to the CSDB on a regular basis upon agreement with:

- (a) the NCB responsible for the DQM of the data related to the relevant issuer in accordance with Article 3 of this Guideline; and
- (b) the ECB for data related to issuers resident outside the euro area, unless a non-euro area NCB has accepted the responsibility for conducting the DQM for data related to issuers resident in its Member State.

3. When providing input data files to the CSDB, NCBs shall provide, as a minimum, information for the attributes covered by Table 1 of Annex I to this Guideline.

4. Input data on securities transmitted to the CSDB shall identify individual securities with their ISIN codes.

5. If an NCB has improved its input data, it shall provide revised input data files to the CSDB or use the CSDB system to correct any errors and omissions in its input data that were not corrected in the course of the verification of the data as specified in Article 5.

6. NCBs shall specify annually the input provision dates they will be using to provide input data files to the CSDB in accordance with the input provision brackets defined by the ECB.

7. In accordance with Article 26 of Guideline (EU) 2018/876 of the European Central Bank (ECB/2018/16) (<sup>5</sup>), NCBs shall ensure that resident issuers of securities are recorded in the ESCB's RIAD data set. NCBs that provide input data files to the CSDB shall include at least one linking entity identifier that is included in RIAD in their input data files.

#### Article 5

#### Data quality management

1. The ECB and NCBs shall carry out initial DQM and regular DQM. In doing so they shall verify item-by-item output feed data and CSEC aggregate statistics, regardless of the source of such data or statistics.

2. DQM shall be applied to DQM targets 1, 2, 3a and 3b and to the corresponding DQM metrics, as specified in Annex II to this Guideline. These metrics shall be based on end-month data that are updated by the ECB on a daily basis subject to the applicable ESCB service level requirements.

3. For the attributes covered by Annex II, the ECB and NCBs shall apply DQM thresholds at a level that ensures the quality of output feed data to support the uses for these attributes as set out in Annex III to this Guideline.

4. The ECB and NCBs shall verify output feed data to the extent that, pursuant to DQM metrics, all DQM exceptions for DQM targets 1, 3a and 3b have been verified to reach the DQM thresholds.

5. The ECB and NCBs shall verify the initial and regular CSEC aggregate statistics to the extent that all DQM exceptions for DQM target 2 have been verified to reach the DQM thresholds.

6. NCBs shall correct input data in accordance with the agreed DQM workflow by using the CSDB system or by providing input data files to the ECB, as appropriate.

<sup>(&</sup>lt;sup>5</sup>) Guideline (EU) 2018/876 of the European Central Bank of 1 June 2018 on the Register of Institutions and Affiliates Data (ECB/2018/16) (OJ L 154, 18.6.2018, p. 3).

#### **Initial DQM**

1. Initial DQM shall be applied to the end-month preview data for the reference month of the current production round.

2. The ECB and NCBs shall verify DQM exceptions to ensure that, after initial DQM has been applied, output feed data and initial CSEC aggregate statistics reflect the most recent developments.

3. When conducting initial DQM, the ECB and NCBs shall rely solely on information that is readily available to them.

#### Article 7

#### **Regular DQM**

1. Regular DQM shall be applied to the data for the reference months prior to the month covered by initial DQM.

2. When conducting regular DQM, the ECB and NCBs shall take into account all currently available information.

#### Article 8

#### Timeline for initial and regular DQM

1. In accordance with the production timetable set out in Table 2 of Annex II to this Guideline, the ECB and NCBs shall verify:

(a) the end-month preview output feed data that are subject to initial DQM;

(b) the output feed data that are subject to regular DQM;

(c) the initial CSEC aggregate statistics;

(d) the regular CSEC aggregate statistics.

2. If the ECB and NCBs identify data quality issues during the verification process, they shall correct these issues in accordance with the same timetable.

#### Article 9

#### Data source management

1. When NCBs identify DSM issues related to commercial data sources, they shall report them to the ECB indicating the relevance of the issues by reference to both their magnitude, in terms of outstanding amounts or market capitalisation of the affected securities, and to the specific output feed data that is affected.

2. The ECB shall report high-relevance DSM issues related to commercial data sources to the respective data providers within one month of the date on which a DSM issue is reported to the ECB. Insofar as possible, the ECB shall use its best efforts to address high-relevance DSM issues in cooperation with the relevant data providers.

3. The ECB shall report DSM issues related to the input data provided by NCBs indicating the relevance of the respective DSM issues by reference to both their magnitude, in terms of outstanding amounts or market capitalisation of the affected securities, and to the specific output feed data that is affected. Within their means, NCBs shall use their best efforts to address high-relevance DSM issues in their input data in cooperation with the ECB.

#### **Compilation of CSEC aggregate statistics**

1. The ECB shall implement arrangements with a view to ensuring that the joint compilation process for the CSEC aggregate statistics follows the compilation rules and methodology specified in Annex IV to this Guideline.

2. The ECB shall compile the monthly CSEC aggregate statistics in the CSDB on a daily basis, as specified in Annex IV to this Guideline, subject to the applicable ESCB service level requirements. CSEC aggregate statistics shall be compiled from reference month December 2020 onwards.

#### Article 11

#### **Output data provision**

- 1. The ECB shall make available to NCBs:
- (a) a snapshot of monthly output feed data as specified in Annex III to this Guideline, on a monthly basis;
- (b) a snapshot of the item-by-item data underlying the CSEC aggregate statistics, and the CSEC aggregate statistics for the previous reference month, on a monthly basis;
- (c) for the previous reference day and on a best efforts basis, a snapshot of daily output feed data as specified in Annex III to this Guideline on a daily basis, covering the most relevant securities as agreed by the ESCB Statistics Committee.
- 2. The ECB shall also make available to NCBs any revisions to the:
- (a) snapshot of output feed data as specified in Annex III to this Guideline;
- (b) snapshot of the item-by-item data underlying the CSEC aggregate statistics and the CSEC aggregate statistics for at least the latest 12 reference months;
- (c) snapshot of the item-by-item data underlying the CSEC aggregate statistics, and the CSEC aggregate statistics for at least the latest 36 reference months, but excluding any period prior to December 2020, on an annual basis.

3. The data referred to in paragraphs 1 and 2 are to be exclusively used for statistical purposes, including the production and compilation of statistics. For non-statistical usage of the data, the rules and procedures for the sharing of confidential statistical information approved by the Governing Council shall be followed.

4. The data referred to in paragraphs 1 and 2 shall be made available either via transmission or via other means commonly accepted by the ECB and the NCBs.

#### Article 12

#### Publication

1. NCBs shall not publish national aggregates or euro area aggregates of securities issues statistics compiled using CSDB data before the respective publication of CSEC aggregate statistics by the ECB. This shall not prevent NCBs from publishing national aggregates of securities issues statistics, whose compilation does not rely on CSDB data, in accordance with national publication timetables.

2. When publishing euro area aggregates of securities issues statistics, NCBs shall accurately reproduce the aggregates published by the ECB.

#### Back data verification requirements in the event of adoption of the euro

Where a Member State whose currency is not the euro adopts the euro following the entry into force of this Guideline, the national central bank of that Member State shall use its best efforts to verify the CSEC aggregate statistics for that Member State at least from reference month December 2020 onwards or for three years prior to the date of the adoption of the euro, whichever date is later.

#### Article 14

#### Simplified amendment procedure

Taking account of the views of the ESCB Statistics Committee, the Executive Board of the ECB shall be entitled to make any necessary technical amendments to the Annexes to this Guideline, provided that such amendments neither change the underlying conceptual framework of the Guideline, including the division of responsibilities between the ECB and the NCBs, nor materially affect the reporting burden on NCBs. The Executive Board shall inform the Governing Council of any amendment to the Annexes to this Guideline without undue delay.

#### Article 15

#### Repeal

1. Guideline 2012/689/EU (ECB/2012/21) and Guideline (EU) 2021/834 (ECB/2021/15) are hereby repealed.

2. References to the repealed Guidelines shall be construed as references to this Guideline and shall be read in accordance with the correlation table in Annex V.

#### Article 16

#### Taking effect and implementation

1. This Guideline shall take effect on the day of its notification to the national central banks of the Member States whose currency is the euro.

2. The national central banks of the Member States whose currency is the euro and the ECB shall comply with this Guideline from 1 June 2022.

#### Article 17

#### Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 19 May 2022.

For the Governing Council of the ECB The President of the ECB Christine LAGARDE

### ANNEX I

## DATA ATTRIBUTES FOR INPUT DATA FOR THE CENTRALISED SECURITIES DATABASE (CSDB)

Where national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') provide input data to the CSDB via debt, equity or price input files they must provide, as a minimum, input information for the following attributes:

Tana data atan'i ara-	Description		Input files	
Input data attribute name	Description	Debt	Equity	Prices
International Security Identification Number (ISIN) code	ISIN security identifier	$\checkmark$	V	
Is active flag	Technical flag required for processing of input records	$\checkmark$	$\checkmark$	$\checkmark$
European System of Accounts (ESA 2010) ( <sup>1</sup> ) instrument classification	Classification of the security pursuant to ESA 2010	$\checkmark$	V	
Primary asset Classification 2 Primary classification of the instrument, e.g. indication of whether the instrument is a debt, equity or fund instrument with some further details		$\checkmark$	V	
Nominal currency	Nominal currency of the instrument (ISO 4217)	$\checkmark$		
Issue price quote convention	Quotation basis of the instrument, e.g. percentage of nominal or currency per share/unit			
Security status	Status of the instrument, indicating whether it is alive or not alive with some further details			
Security status date	Security status date Date corresponding to an event when the security's status changed		V	
Issuer source code	Issuer code of a CSDB input data source. For input data provided by NCBs, this is the linking entity identifier between the CSDB and the Register of Institutions and Affiliates Database (RIAD)	$\checkmark$	V	
Issuer source code type	Type of issuer source code	$\checkmark$		
Issuer domicile country	Country of legal incorporation (domicile) of the issuer of the security (ISO 3166)		V	
Issuer name	Complete name of the issuer	$\checkmark$	$\checkmark$	
ESA 2010 issuer sector	Institutional sector of the issuer pursuant to ESA 2010	$\checkmark$		
Price date	Date of the price information			$\checkmark$
Close price	Value of the security's price at close			$\checkmark$
Price quotation type	Type of price quotation, e.g. percentage of nominal value or currency per share/unit			

#### Table1

Input data attribute name	Description	Input files		
	Description	Debt	Equity	Prices
Price reference market	Market on which the price was quoted (ISO 10383)			
Price currency	Currency, in which the price is quoted (only relevant when the quotation type is in currency)			$\checkmark$
Issuer LEI code	Legal entity identifier (LEI) of the issuer (ISO 17442), if the issuer has an LEI (*)	$\checkmark$	$\checkmark$	

(<sup>1</sup>) As established by Regulation (EU) No 549/2013.
(\*) The LEI must be reported if this information is available to the NCB.

NCBs that provide input data to the CSDB must use their best efforts to provide input information for the following attributes:

T . 1		Input files		
Input data attribute name	Description	Debt	Equity	Prices
Amount outstanding	Outstanding amount (at face value)	$\checkmark$		
Number outstanding	Total number of individual shares or fund shares/units currently outstanding		V	
lssue price	Issue price of individual securities as paid by the investors	$\checkmark$	√	
Redemption price	Final redemption price of individual securities	$\checkmark$		
Issue date	Date on which the securities were delivered to the underwriter by the issuer against payment. This is the date when the securities were available for delivery to investors for the first time		~	
Maturity date	Original maturity date, i.e. the date of the final contractually scheduled principal payment as defined in the prospectus	$\checkmark$		
Tranche amount	Amount of the tranche (in nominal currency)	$\checkmark$		
Tranche date	Date when a new tranche of an existing security was issued	$\checkmark$		
Tranche price	Price at which a new tranche of an existing security was offered to the market	$\checkmark$		
Partial redemption amount	Amount of the partial redemption (in nominal currency)	$\checkmark$		
Partial redemption date	Date when an existing security was partially redeemed	$\checkmark$		
Partial redemption price	Price at which an existing security was partially redeemed	$\checkmark$		
Capital increase amount	increase amount Amount of the capital increase (in number of individual shares)		V	
Capital increase date	Date when the capital increase took place		$\checkmark$	

#### Table 2

22.6.2022

Innut data attributa noma	Description	Input files		
Input data attribute name	Description	Debt	Equity	Prices
Capital increase price	Price at which new shares were offered to the market		$\checkmark$	
Capital decrease amount Amount of the capital decrease (in number of individual shares)			V	
Capital decrease date	Date when the capital decrease took place		√	
Capital decrease price	Price at which existing shares were bought back and subsequently cancelled		$\checkmark$	
Asset securitisation type	Type of securitised assets			
Instrument seniority type	Astrument seniority type Classification of whether the instrument is guaranteed or not, what rank/level it has, and whether it is secured or not			
Coupon-related attributes	Coupon-related attributes Information on coupon payments including coupon type, coupon frequency, coupon dates, coupon rates and accrual start date			
Split factor	Split factor for stock splits (and reverse splits) of shares, defined as (number of shares before the split) / (number of shares after the split)		$\checkmark$	
Stock split date	Date when the stock split occurred		$\checkmark$	
Dividend amount	ividend amount Amount of the last dividend payment (in currency units)		$\checkmark$	
Dividend amount type	Type of dividend distribution (e.g. in cash or in kind)		$\checkmark$	
Dividend currency	Currency of the last dividend payment (ISO 4217)		$\checkmark$	
Dividend settlement date	Date of the last dividend payment		$\checkmark$	
Dividend frequency	Frequency of dividend payments		$\checkmark$	
Income amount	Income attributable to fund investors, including dividends and retained earnings (ESA 2010 concept) - only relevant for fund shares/units		V	
Income currency	Currency of income attributable to fund investors (ISO 4217) - only relevant for fund shares/units		$\checkmark$	
ncome date	Date to which the income amount refers to, i.e. the end of the month or end of the quarter - only relevant for fund shares/units		$\checkmark$	
Fund asset structure	Type of (majority of) underlying fund assets		√	
Fund geographical structure	Geographical split of (majority of) underlying fund assets		$\checkmark$	

Innut data attaileuta noma	Description	Input files		
Input data attribute name	Description	Debt	Equity	Prices
Fund type	Type of fund, i.e. classification as open or closed fund and of dividend policy (distributing or non- distributing)		$\checkmark$	
Instrument supplementary information	Information on whether the security is, e.g., stripped, is a depository receipt, is a warrant, or is relevant for securities issues statistics produced from CSDB item- by-item data (hereinafter 'CSEC aggregate statistics')	$\checkmark$	$\checkmark$	

# DATA QUALITY MANAGEMENT (DQM) TARGETS, IMPLEMENTATION OF EXCEPTIONS, ATTRIBUTES, DQM THRESHOLD BASIS AND TIMELINE

The Centralised Securities Database (CSDB) DQM framework is based, first, on DQM targets that represent benchmarks for assessing the quality of output feed data and, second, on DQM metrics that measure the level to which a certain DQM target has been reached and thereby identify and prioritise, for each respective DQM target, the output feed data that need to be verified. It is also based on DQM thresholds that define the minimum level of verification that needs to be conducted in relation to a DQM target and on DQM exceptions that are identified via a specified rule and that present (potential) data quality issues to be verified or corrected in order to reach the respective DQM threshold.

ANNEX II

The DQM targets, DQM metrics, implementation of DQM exceptions, attributes and DQM threshold basis are specified in the following table. In the CSDB, a list of DQM exceptions will be made available for each DQM target that must be verified in order to reach the DQM threshold. The ECB and the national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') will verify the DQM exceptions defined in this Annex, for which DQM exception rules are implemented in the CSDB.

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
Target 1:	Concept:	Target 1 assesses the stability of stock data.	Explicit attributes: Issue date, maturity date for debt, nominal currency,	Amounts outstanding or market capitalisation in euro,
Data stability – stock data	The metric will be defined for each country of residence/sector combination as a volume weighted 'index of change', weighted with monetary amounts. An index value of 1 indicates that the respective attribute has not changed for any of the underlying securities, while an index value of 0 indicates that the respective attribute has changed for all securities. If an index drops below 1, individual securities will be identified with the changed attribute that has caused the index drop with a view to verifying the change until the threshold is met.	<ul> <li>Any month-on-month difference triggering an index change triggers a DQM exception for the output feed data attributes covered by Target 1.</li> <li>Unverified DQM exceptions must not decrease the share of stable data beyond the DQM threshold for each of the following European System of Accounts (ESA 2010) (<sup>2</sup>)issuer sectors:</li> <li>S.11 'non-financial corporations'</li> <li>S.121 'the central bank'</li> <li>S.122 'deposit-taking corporations except the central bank'</li> </ul>	quotation basis, ESA 2010 instrument classification, primary asset classification 2, CSDB issuer identifier, issuer domicile country, ( <sup>1</sup> ) ESA 2010 issuer sector, issuer European Classification of Economic Activities (NACE) classification, entity status,	expressed as share of stock data.

#### Table 1

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
	Events triggering an index change: For discrete attributes, any month-on- month difference in the attribute is considered to trigger an index change. For continuous attributes, any month- on-month difference larger than a specified threshold is considered to trigger an index change. <i>Coverage:</i> This DQM metric covers all investment fund shares, equity and debt securities including certificates.	<ul> <li>S.123 'money market funds (MMFs)'</li> <li>S.124 'non-MMF investment funds'</li> <li>S.125 'other financial intermediaries, except insurance corporations and pension funds'</li> <li>S.126 'financial auxiliaries'</li> <li>S.127 'captive financial institutions and money lenders'</li> <li>S.128 'insurance corporations (IC)'</li> <li>S.129 'pension funds (PF)'</li> <li>S.13 'general government'</li> </ul>		
Target 2: Data accuracy – CSEC aggregate statistics	Conceptual background: CSEC aggregate statistics for end- month stocks and monthly flows are produced from CSDB output data on a daily basis, as specified in Annex IV to this Guideline. As CSEC aggregate statistics consist of a large number of different aggregates, including higher-level and overlapping aggregate statistics must focus on sets of 'CSEC priority series', i.e. the lowest- level CSEC aggregate statistics that are subject to DQM requirements, as specified in Annex IV to this Guideline. Verifying the sets of priority series will ensure that all higher-level aggregates	<ul> <li>Target 2 assesses the data quality of the CSEC aggregate statistics</li> <li>Any CSEC priority series for debt securities and listed shares triggers a DQM exception for Target 2.</li> <li>Unverified DQM exceptions shall not exceed the DQM threshold for debt securities and listed shares.</li> </ul>	Implicit attributes: Issue date, maturity date for debt, nominal currency, quotation basis, ESA 2010 instrument classification, primary asset classification 2, issuer domicile country, ( <sup>3</sup> ) ESA 2010 issuer sector, entity status, amount outstanding, number outstanding, tranche amount, tranche issue date, tranche issue price, security status, coupon-related attributes, price value, issue price, redemption price, instrument supplementary information.	Stocks at market value of CSEC priority series expressed as a share of stocks at market value of the CSEC total economy aggregates of that country (separately calculated for debt securities and listed share aggregates).

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
	that are based on these series and to a significant extent also related overlapping aggregates are verified as well.			
	Concept:			
	For each country, the metric must identify the 'CSEC priority series' and must relate them, as a percentage of amounts outstanding or market capitalisation, to the total economy aggregates for stocks at market value for that country.			
	It must be possible to access disaggregated data at the level of the individual securities underlying the CSEC aggregate statistics. The sets of CSEC priority series must be verified and confirmed until the threshold is met.			
	<i>Coverage:</i> The metric covers debt securities and listed shares that are within the scope of			
	CSEC aggregate statistics.			
arget 3a: Pata accuracy – support prrect sector allocation nd data extraction by suer	Conceptual background: The CSDB links issuer and instrument information on a relational basis which can be described as 'one to many', i.e. one issuer can be related to many instruments, while each instrument is related to only one issuer. This instrument-issuer link is made via	Target 3a assesses the correct identification of the issuer population. Any disagreement on the issuer of an instrument, i.e. instruments in 'clash groups', triggers a DQM exception for Target 3a.	Explicit attributes: Issuer identifier used for grouping.	Amounts outstanding and market capitalisation in euro referring to instruments in clash groups, expressed as a percentage share of all instruments.

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
	individual issuer identifiers provided by the different input data providers. These identifiers differ between the data providers as there is, so far, no common standard but they should be consistent.	Where there is a DQM exception, the instruments for this exception must not exceed the DQM threshold.		
	If input data providers provide inconsistent (clashing) issuer identifiers for the same instrument, i.e. if they disagree on the issuer, the instrument cannot be allocated to a definite issuer and ends up in a 'clash group'. Clash groups can still be classified correctly by country and sector but there is no consistent link to the relevant issuer of the instrument.			
	Instruments in clash groups prevent the consistent and reliable extraction of all instruments issued by a certain issuer. Instruments in clash groups increase			
	the risk of misclassification by country of residence or sector. <i>Concept:</i>			
	For each country of residence the metric must identify the instruments in clash groups and relate them as a percentage share in terms of counts or in terms of monetary amounts to all instruments for that country.			

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
	<i>Coverage:</i> The metric covers all instruments in the CSDB.			
Target 3b: Data accuracy – support correct sector allocation and data extraction by issuer	Conceptual background:The CSDB links issuer and instrumentinformation on a relational basis whichmay be described as 'one to many', i.e.one issuer can be related to manyinstruments while each instrument isrelated to only one issuer. Thisinstrument-issuer link is made viaindividual issuer identifiers which areprovided by the different input dataproviders. These identifiers differbetween the data providers as there is,so far, no common standard but theyshould be consistent.If no data provider provides an issueridentifier for a given instrument, there isa risk that this instrument will not beallocated to a definite issuer and will endup in a 'stand-alone group' consistingonly of this instrument. Stand-alonegroups may still be classified correctlyby country and sector but there is noconsistent link to the relevant issuer of the instrument.Instruments in stand-alone groups prevent the consistent and reliableextraction of all instruments issued by a certain issuer.	Target 3b assesses the correct identification of the issuer population. Any lack of reliable information on the issuer of an instrument, i.e. instruments in 'stand-alone groups', triggers a DQM exception for Target 3b. Where there is a DQM exception, the instruments for this exception must not exceed the DQM threshold.	Explicit attributes: Issuer identifier used for grouping.	Amounts outstanding and market capitalisation in euro referring to instruments in stand-alone groups, expressed as a percentage share of all instruments.

DQM target	DQM metrics	Implementation of DQM exceptions	Output feed data attributes	DQM threshold basis
	Instruments in stand-alone groups increase the risk of misclassification by country of residence or sector, given that they are often provided with incomplete information.			
	Concept:			
	For each country of residence the metric must identify the instruments in stand- alone groups and relate them as a percentage share in terms of counts or in terms of monetary amounts to all instruments for that country.			
	Coverage:			
	The metric covers all instruments in the CSDB.			

(1) Input data for issuer attributes is transmitted to the CSDB from the Register of Institutions and Affiliates Database (RIAD) data set on a regular basis in accordance with Article 4 of this Guideline. (7) Input data for issuer attributes is transmitted to the CSDB from the RIAD data set on a regular basis. RIAD input data is linked with the CSDB data in accordance with Article 4(7) of this Guideline.
 (8) Input data for issuer attributes is transmitted to the CSDB from the RIAD data set on a regular basis. RIAD input data is linked with the CSDB data in accordance with Article 4(7) of this Guideline.

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When performing their tasks under Article 8 of this Guideline, the ECB and NCBs must adhere to the following timetable for the verification of DQM exceptions and correction of data
quality issues for DQM targets 1, 2, 3a and 3b:
Table 2

Type of DQM	Reference months subject to DQM	Type of data subject to DQM	DQM targets, for which exceptions must be verified and data quality issues be corrected	Deadline for verification of all exceptions to reach the DQM thresholds
Initial DQM	Reference month of current production round	End-month preview output feed data	DQM targets 1, 3a and 3b	End of the third working day following the reference month subject to initial DQM
		Initial CSEC aggregate statistics	DQM target 2	End of the seventh working day following the reference month subject to initial DQM
Regular DQM	All earlier reference months	Output feed data	DQM targets 1, 3a and 3b	End of the third working day following the reference month subject to initial DQM
		Regular CSEC aggregate statistics	DQM target 2	End of the seventh working day following the reference month subject to initial DQM

A specific example of the timetable for the verification of DQM exceptions and correction of data quality issues for DQM targets 1, 2, 3a and 3b is provided in the following diagram. The example illustrates the case of the production round for reference month June 2022. In this case, the ECB and NCBs must conduct **initial** DQM of DQM exceptions referring to reference month June 2022 by the third working day of July 2022 in the case of DQM exceptions for DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM exceptions referring to reference months by the third working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 and any earlier reference months by the third working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM exceptions for DQM targets 1, 3a and 3b and by the seventh working day of July 2022 in the case of DQM exceptions for DQM targets 2.

# Figure

# Example of the timeline for the verification of DQM exceptions for reference month June 2022.

May 2022 and earlier reference months	June 2022	July 2022							
		3 <sup>rd</sup> working day of July 2022	7 <sup>th</sup> working day of July 2022						
Exceptions raised for data referring to reference month May 2022 and earlier reference months shall be subject to <b>regular</b> DQM	Exceptions raised for data referring to reference month June 2022 will be subject to <b>initial</b> DQM	Deadline for verification of exceptions and correction of data quality issues for DQM targets 1, 3a and 3b for all reference periods	Deadline for verification of exceptions and correction of data quality issues for DQM target 2 for all reference periods						

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#### ANNEX III

# FEEDS AND OUTPUT FEED DATA ATTRIBUTES COVERED BY THE DATA QUALITY MANAGEMENT (DQM) FRAMEWORK

**Monthly output feed data**: The DQM framework covers the following monthly item-by-item output feeds which support the production of statistics:

- CSEC feed supporting CSEC aggregate statistics, which are securities issues statistics produced from output data from the Centralised Securities Database (CSDB), (hereinafter the 'CSEC feed')
- External feed supporting external statistics (hereinafter the 'EXT feed')
- Financial vehicle corporations (FVCs) feed supporting statistics on financial vehicle corporations (hereinafter the 'FVC feed')
- Investment fund feed supporting statistics on investment funds (hereinafter the 'IF feed')
- Securities holdings feed supporting securities holdings statistics (hereinafter the 'SHS feed')
- Government securities funding feed supporting statistics on government securities funding (hereinafter the 'GSF feed')
- Insurance corporations feed supporting statistics on insurance corporations (hereinafter 'IC feed')
- Pension funds feed supporting statistics on pension funds (hereinafter 'PF feed')

**Daily output feed data**: The DQM framework covers the following daily item-by-item output feeds which support different uses and for which the European Central Bank (ECB) national central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') will use their best efforts in ensuring the quality of the output feed data:

- Feed supporting collateral management (hereinafter 'CM feed')
- Feed supporting money market statistical reporting (hereinafter 'MM feed')
- Feed supporting securities financing transactions data store (hereinafter 'SFT feed')

Output feed data attributes covered by the DQM framework:

Output feed data	Description		Applicable feed										
attribute name	Description	CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT	
International Securities Identification Number (ISIN) code	ISIN security identifier (ISO 6166).	$\checkmark$	$\checkmark$	$\checkmark$	V	$\checkmark$							
Classification of Financial Instruments (CFI) code	CFI code of the instrument (ISO 10962).									$\checkmark$	$\checkmark$	$\checkmark$	
Central securities depository	Code of the central securities depository, i.e. where the material or immaterial security is actually stored and managed									V			

Output feed data	Description					App	licable	feed				
attribute name	Description	CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
European System of Accounts (ESA 2010) instrument classification	Classification of the security pursuant to ESA 2010.	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	V	$\checkmark$			V
Debt type	Type of debt instrument.					$\checkmark$	$\checkmark$			$\checkmark$		
Primary asset classification 2	Primary classification of the instrument (e.g. indicating whether the instrument is a debt security, equity security or fund with some further details)	1									$\checkmark$	V
Security is included in CSDB-based securities issues statistics (hereinafter 'CSEC')	An attribute which can be used to identify securities that should be included in 'current outstanding amounts', in line with the scope of CSEC aggregate statistics.	1					$\checkmark$			V		
Instrument supplementary information	Supplementary attribute indicating whether an instrument should be included in CSEC or not.	V					V	V	V	V		
Security status	Status of the instrument. This attribute indicates whether an instrument is alive or not.	V					V	V	V	V		
Security status date	Attribute indicating the date at which the security status attribute has changed from alive to not-alive (or from non-alive to alive).	V						$\checkmark$	$\checkmark$	$\checkmark$		

Output feed data	Description					App	olicable	feed				
attribute name	Description	CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
Asset securitisation type	Type of securing asset.			$\checkmark$		$\checkmark$				V		
Instrument seniority type	Attribute indicating whether the instrument is guaranteed or not, its rank/level, and whether it is secured or not.									$\checkmark$		
Security is included in the Collateral and Counterparties Database	Attribute indicating whether an instrument is eligible to be pledged as collateral for Eurosystem credit operations.					$\checkmark$				$\checkmark$		
Nominal currency	Nominal currency of the instrument (ISO 4217).	$\checkmark$	V	$\checkmark$								
Issue Date	The date on which the securities are delivered to the underwriter by the issuer against payment. This is the date when the securities were available for delivery to investors for the first time	V	V	V	1	V	V	V	V			V
	Note: For a strip, this column indicates the date on which the coupon/principal is stripped.											
Maturity date	Original maturity date, i.e. the date of the final contractually scheduled principal payment as defined in the prospectus.	$\checkmark$	V	V	$\checkmark$	V	V	V	V	V		V

Output feed data	Description					App	olicable	feed				
attribute name	Description	CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
Original maturity	The original maturity of an instrument in days calculated at the date the output data were produced. Empty if no maturity date is available.	1										V
Residual maturity	The residual maturity of an instrument in days calculated on the date the output data are produced.	$\checkmark$					V					V
Issuer name	Name of the issuer									$\checkmark$	$\checkmark$	$\checkmark$
Issuer organisation alias code	Issuer's source alias code or issuer's external alias code according to the alias type.									V		
Issuer organisation alias type	Issuer organisation alias type indicating the data provider that has provided the alias code or external alias code.									V		
ESCB issuer identifier	An issuer identification code loaded via a dedicated list corresponding to a type defined in the ESCB issuer identifier type code list.									V		
ESCB issuer identifier type	The type of ESCB issuer identifier indicating the official ECB code list the identifier is part of (e. g. monetary financial institution (MFI) list, investment fund (IF) list, financial vehicle corporation (FVC) list, or insurance									V		

Output feed data	5					App	olicable	feed				
attribute name	Description	CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
	corporations and pension funds (ICPF) list)											
Issuer domicile country	Country of legal incorporation (domicile) of the issuer of the security (ISO 3166).	$\checkmark$	V	V		V	V	V	V	V	V	V
ESA 2010 issuer sector	Institutional sector of the issuer pursuant to ESA 2010.	$\checkmark$	V	V	$\checkmark$	V	V	V	V	V	V	V
Issuer European Classification of Economic Activities (NACE) classification	Main economic activity pursuant to NACE.		$\checkmark$					V	V	V		V
Entity status	Entity status of the issuer of the instrument. This attribute indicates whether an issuer is alive or not.	V										
Entity status date	Attribute indicating the date on which the entity status attribute changed from alive to not-alive (or from not-alive to alive).	V										
Issuer legal entity identifier (LEI)	LEI code of the issuer (ISO 17442).									V	V	$\checkmark$
Issuer MFI code	MFI code of the issuer.									$\checkmark$		$\checkmark$
Amount issued	Amount of the debt instrument that has been raised at issue (in face value).						V			$\checkmark$		

Output feed data	Description					App	licable	feed				
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
	For a strip, this column indicates the amount the coupon/ principal was stripped at. For a security issued in tranches, under the same ISIN, this column indicates the cumulative amount issued so far. The amount issued is denominated in nominal currency.											
Amount outstanding	Outstanding amount (in face value). For a security issued in tranches, under the same ISIN, this column indicates the cumulative amount issued so far, net of redemptions. Values are given in nominal currency.	V	V			V	V	V	V	V		V
	Amount outstanding is denominated in nominal currency. If nominal currency is missing, the amount outstanding is denominated in euro.											
Amount outstanding in euro	Amount outstanding converted into euro using the euro exchange rate vis-à- vis nominal currency valid at the date the output data were produced.	$\checkmark$				$\checkmark$	$\checkmark$	V	$\checkmark$			$\checkmark$

Output feed data	Description	Applicable feed										
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
Amount outstanding type	Attribute indicating whether the amount outstanding attribute captures total outstanding amounts or the number of instruments outstanding.	1								V		V
Market capitalisation	Latest available market capitalisation. Market capitalisation is denominated in nominal currency. If nominal currency is missing, market capitalisation is denominated in euro.	$\checkmark$				V		$\checkmark$	1			
Market capitalisation in euro	Market capitalisation converted into euro using the euro exchange rate vis-à- vis nominal currency valid at the date the output data were produced.	V						V	V			V
Tranche issue date	Date on which a new tranche of an existing security was issued.	V										
Tranche issue price	Price at which a new tranche of an existing security was offered to the market.	$\checkmark$										
Partial redemption date	Date on which an existing security was partially redeemed.	V										
Partial redemption price	Price at which an existing security was partially redeemed.	$\checkmark$										

Output feed data	Description	Applicable feed										
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
Capital increase date	Date on which the capital increase took place	$\checkmark$										
Capital increase price	Price at which new shares were offered to the market	$\checkmark$										
Capital decrease date	Date on which the capital decrease took place	$\checkmark$										
Capital decrease price	Price at which existing shares were bought back and subsequently cancelled	V										
Yield to maturity	Security specific yield to maturity in percentage terms.					V	V					$\checkmark$
Short name	Short name of the instrument, defined on the basis of the characteristics of the issue and any available information.						V			V	1	
Pool factor	For mortgage backed securities, pool factor or remaining principal balance factor is the outstanding principal balance of the mortgage pool underlying the security divided by original principal balance.		1	V	$\checkmark$	√	V	V	~	1		
Has embedded options	Attribute indicating whether the instrument has an embedded redemption option.									V		

Output feed data	Description	Applicable feed										
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT
Quotation basis	Quotation basis of the instrument, e.g. percentage of nominal (percent) or currency per share/unit (units).	1	V	V	V	V	V	V	V	V		V
Price date	Date that the price information provided in 'Price value' refers to.	V								V		V
Price value	Last available representative price of the instrument at the reference date expressed in the quotation basis and the nominal currency, if applicable, of the instrument. For interest bearing securities, the clean price is provided, i.e. excluding accrued interest.	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	V	$\checkmark$	V	V		V
Price value type	Nature of price value, i.e. if it represents a market valuation, estimated or a default value.		V	V	$\checkmark$	V	$\checkmark$	V	V	V		V
Monthly average price	Average of normalised prices of the instrument available in the last 30 calendar days up to the reference date expressed in the quotation basis and the nominal currency, if applicable, of the instrument.	V	$\checkmark$			V				~		

Output feed data	Description	Applicable feed											
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT	
Issue price	Issue price of individual securities as paid by the investors.	V											
Redemption type	Redemption type, e.g. whether it is bullet, perpetual, structured, annuity, serial, irregular, or stepped.						V			$\checkmark$			
Redemption frequency	Number of redemptions per year for a debt instrument.						V			V			
Redemption currency	Currency of the payment of the principal (ISO 4217).									V			
Redemption price	Final redemption price of individual securities.	$\checkmark$					$\checkmark$			V			
Accrual start date	Date on which the interest starts to accrue for interest paying debt instruments	V								V		V	
Accrued interest	Interest accrued since the last coupon payment or since the accrual start date. For interest bearing securities, adding this value to the price value results in the so-called 'dirty price'.	√	1	1	1		1	1	1	1		V	
Accrued income factor	Daily security specific income factor in percentage, calculated following the debtor approach. The factor is based on accruals, i.e. giving the combined effect	√	√	$\checkmark$	V	$\checkmark$		V	$\checkmark$	√		V	

Output feed data	Description	Applicable feed											
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT	
	of accrued interest and income due to difference in issue and redemption price.												
Accrued income (Creditor)	Daily, security specific income, in %, calculated following the creditor approach.									V			
Coupon type	Type of coupon, e.g. whether it is fixed, floating, stepped etc.	$\checkmark$				$\checkmark$	$\checkmark$	$\checkmark$	V	V		V	
Last coupon rate	Last coupon rate in percentage per annum actually paid (annualised rate).	V	V	$\checkmark$	$\checkmark$	V		$\checkmark$	V	V			
Last coupon date	Date of last coupon rate actually paid. The attribute allows for identification of whether the last coupon rate actually paid falls within the reporting period or not.	V	1	1	1	1		1	1	1			
Last coupon frequency	Frequency per year at which the last coupon rate is paid out.	V	V	V	V	V		V	V	V			
Coupon currency	Coupon currency (ISO 4217).	$\checkmark$						V	$\checkmark$	$\checkmark$			
Dividend amount	Amount of the last dividend payment per share (in dividend amount type) before tax (gross dividend).		V			V			V			V	

Output feed data	Description	Applicable feed											
attribute name		CSEC	EXT	FVC	IF	SHS	GSF	IC	PF	СМ	MM	SFT	
Dividend amount type	Dividend amount per share may be denominated in dividend currency or in number of shares.		V		V	V		V	V				
Dividend currency	Currency of the last dividend payment (ISO 4217).		$\checkmark$		$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$			V	
Dividend Settlement date	Settlement date of the last dividend payment. The attribute permits to identify whether the dividend amount paid falls within the reporting period or not.		1		1	1		1	1			V	
Last split factor	Split factor for stock splits (and reverse splits) of shares, defined as (number of shares before the split) / (number of shares after the split).	V	V		V	V		V	V				
Last split date	Date as of which the stock split becomes effective.	$\checkmark$			$\checkmark$			$\checkmark$	$\checkmark$				
Fund asset structure type	Type of (majority of) underlying assets of the fund.							$\checkmark$	V				

#### ANNEX IV

#### **CSEC AGGREGATE STATISTICS**

#### Introduction

Centralised Securities Database (CSDB)-based securities issues statistics (hereinafter 'CSEC') provide stock and flow aggregates on securities issuances by residents of the Member States whose currency is the euro (hereinafter the 'euro area Member States') and of the Member States whose currency is not the euro (hereinafter the 'non-euro area Member States') in all currencies, as well as by residents of the rest of the world (RoW) in euro, broken down by sector of the issuer, instrument type, interest rate type, maturity, and currency of denomination.

National central banks of the Member States whose currency is the euro (hereinafter the 'NCBs') are responsible for verifying CSEC aggregate statistics related to issuers resident in their countries. The ECB is responsible for verifying CSEC aggregate statistics related to issuers resident outside the euro area, unless an NCB of a Member State whose currency is not the euro (hereinafter a 'non-euro area NCB') has accepted the responsibility of verifying the CSEC aggregate statistics related to issuers resident.

The methodology for compiling CSEC aggregate statistics follows as closely as possible the international standards defined in the 'Handbook on Securities Statistics' of the Bank for International Settlements, the European Central Bank (ECB) and the International Monetary Fund (<sup>1</sup>) and in the ESA 2010 (<sup>2</sup>). Exceptional cases where the methodology deviates from these statistical standards are specifically highlighted. The detailed CSEC calculation rules will be defined in the compilation guide agreed by the ESCB Statistics Committee and published in the ECB's website.

### 1. Coverage and classifications

- 1.1. Residency of the issuer: CSEC aggregate statistics cover issuances by residents of euro area and non-euro area Member States in all currencies, as well as by residents of the RoW in euro. Issuances by residents of euro area and/ non-euro area Member States are broken down by issuer country and other criteria. In addition, euro area and Union level aggregates also cover issuances by supranational institutions deemed resident in the euro area and the Union as a whole respectively.
- 1.2. Sectors: CSEC aggregate statistics cover issuances by the following issuer sectors:
  - S1: total economy (all sectors combined)
  - S11: non-financial corporations
  - S12: financial corporations
  - S121: central banks
  - S122: deposit taking corporations except the central bank
  - S12M: financial corporations other than deposit taking corporations
  - S12P: financial corporations other than deposit taking corporations, insurance corporations and pension funds
  - S124: non-money market fund investment funds
  - S125: other financial intermediaries, except insurance corporations and pension funds
  - S125A: financial vehicle corporations engaged in securitisation
  - S125W: other financial intermediaries except insurance corporations and pension funds (excluding financial vehicle corporations engaged in securitisation)
  - S126: financial auxiliaries
  - S127: captive financial institutions and money lenders
  - S12Q: insurance corporations and pension funds

<sup>(1)</sup> Available on the International Monetary Fund's website at www.imf.org.

 $<sup>(^2)</sup>$  As established by Regulation (EU) No 549/2013.

- S13: general government
- S1311: central government (excluding social security funds)
- S13M: state and local government (excluding social security funds)
- S1314: social security funds
- S1M: households and non-profit institutions serving households
- 1.3. Instrument type: CSEC aggregate statistics cover issuances of debt securities and listed shares (3). Issuances of unlisted shares, other equity, shares/units issued by money market funds (MMF) and shares/units issued by non-MMF investment funds are excluded.

Issuances of debt securities and listed shares include only securities identified with an International Securities Identification Number (ISIN) code. Issuances of non-negotiable instruments including loans, transactions in securities as part of repurchase agreements, and government investments in the capital of international organisations that are legally constituted as corporations with share capital are excluded.

- 1.4. *Interest rate type:* CSEC aggregate statistics cover issuances of debt securities of all interest rate types with the following breakdowns:
  - Fixed coupon: Debt securities for which at the date of issue the contractual nominal coupon payments are fixed in terms of the currency of denomination for the life of the debt security and the principal repayment is fixed in terms of the currency of denomination and time. This includes stepped debt securities for which at the date of issue different coupons are prefixed throughout the life of the security.
  - Zero coupon: Single-payment debt securities without coupon payments, usually sold at a discount.
  - Inflation-linked variable rate: Debt securities for which coupon or principal payments are linked to price indices.
  - Interest rate-linked variable rate: Debt securities for which coupon or principal payments are linked to interest rate benchmarks or bond yields.
  - Asset price-linked variable rate: Debt securities for which coupon or principal payments are linked to any other financial assets, commodities, or indices different from price indices or interest rate benchmarks. This includes debt securities linked to baskets of securities, currencies, business events such as issuer defaults, and other types of assets or events.

Debt securities that contain a variable coupon combined with a fixed coupon are classified under the relevant variable interest rate category.

- 1.5. *Maturity:* CSEC aggregate statistics cover issuances of debt securities of all maturities. The maturity breakdown for issuances of debt securities classifies debt securities by original maturity and to some extent by residual maturity.
- 1.6. *Currency of denomination:* CSEC aggregate statistics cover issuances by euro area residents broken down into euro and 'other currencies', issuances by residents of non-euro area Member States broken down into euro, 'national currency other than euro' and 'other currencies', and issuances by RoW residents in euro. The table below summarises the currency breakdowns.

Currency of denomination	Issuances by euro area residents	Issuances by non-euro area Member State residents	Issuances by RoW residents
In euro	$\checkmark$	$\checkmark$	$\checkmark$
In national currency other than euro	N/A	$\checkmark$	
In other currencies	$\checkmark$	$\checkmark$	

<sup>(&</sup>lt;sup>3</sup>) Categories F.3 and F.511 of the ESA 2010.

### 2. Stock and flow concepts

CSEC aggregate statistics provide information on stocks (i.e. outstanding amounts) and flows (i.e. gross issuances, redemptions, revaluations, and other changes in volume including reclassifications). The equation below illustrates the link between stocks and flows:

Stocks (t) = Stocks (t-1) + Gross issuances (t) - Redemptions (t) + Revaluations (t) + Other changes in volume (t)

- 2.1. *Stocks:* CSEC aggregate statistics on stocks cover positions of debt securities and listed shares that are outstanding at the end of the reference period.
- 2.2. Gross issuances: CSEC aggregate statistics on gross issuances cover new issuances of debt securities and listed shares during the reference period. Issuances refer to the situation where an issuer sells newly created debt securities or listed shares to holders. A security is considered to have been issued when the issuer transfers it to a holder, usually in exchange for currency or transferable deposits, or when it has been effectively issued but retained by the original issuer (<sup>4</sup>). In addition, for aggregates on debt securities at nominal and market value, gross issuances also include accrued interest. Gross issuances are not recorded in the event of a sole listing of a corporation on a stock exchange where no new capital is raised (<sup>5</sup>). Issues of securities which can later be converted into other instruments must be recorded as issues in their original instrument category; on conversion they are to be recorded as having been redeemed from this instrument category, with an identical amount then treated as gross issues in a new category.
- 2.3. *Redemptions:* CSEC aggregate statistics on redemptions cover cancellations of debt securities and listed shares during the reference period. Redemptions include debt securities that have reached their maturity date or have been redeemed early, as well as listed shares that have been formally cancelled. In addition, for aggregates of debt securities at nominal and market value redemptions also include paid coupon. Redemptions are not recorded in the event of a sole delisting from a stock exchange (<sup>6</sup>).
- 2.4. *Revaluations:* CSEC aggregate statistics on revaluations cover revaluations for debt securities and listed shares accrued during the reference period. Revaluations may occur as a result of market developments of prices and exchange rates.
- 2.5. Other changes in volume: CSEC aggregate statistics on other changes in volume cover other changes in volume for debt securities and listed shares due to changes in the quantity or physical characteristics of securities or changes in the classification of securities. Changes in classification comprise changes in the institutional sector of the issuer, changes of the reference area in which an issuer is domiciled, changes to the structure of institutional units, and changes in the classification of assets. Other changes in volume are derived as a residual from the stock-flow equation.

The detailed calculation rules for stocks and flows will be defined in the compilation guide agreed by the ESCB Statistics Committee and published on the ECB's website.

#### 3. Statistical treatment of specific instrument categories

In compiling CSEC aggregate statistics, the following treatment of specific instrument categories should be applied:

**Depository receipts**: To avoid double counting, issuances of depository receipts must be excluded from CSEC aggregate statistics.

<sup>(4)</sup> Securities are considered as effectively issued (even if they have not been sold to another entity before) when: (i) they are recorded in the accounting balance sheet of the issuer; or (ii) they are used or are available for use by the issuer for market operations.

<sup>(5)</sup> By contrast, the ESA 2010 (5.150) theoretically allows the recording of such transactions, as it states: Listing is recorded as an issuance of listed shares, and as a redemption of unlisted shares [...] where appropriate.

<sup>(&</sup>lt;sup>6</sup>) By contrast, the ESA 2010 (5.150) theoretically allows the recording of such transactions, as it states: '[...] de-listing is recorded as a redemption of listed shares, and an issuance of unlisted shares *where appropriate*.'

**Issuances with multiple ISIN codes**: To avoid double counting, issuances, which are identified by multiple ISIN codes (e.g. because different portions of a security are issued under different regulatory rules or deposited with different depositories), must be included in CSEC aggregate statistics only to the extent that the respective outstanding amounts are not already covered under a different ISIN code.

**Stripped debt securities**: To avoid double counting, issuances of stripped debt securities must be included in CSEC aggregate statistics only to the extent that the respective outstanding amounts are not already covered by the respective original debt security.

**Holdings of own securities**: CSEC aggregate statistics must be compiled on a gross basis and cover own holdings of securities, including (i) securities sold in the market and bought back by the issuer and (ii) securities which have been effectively issued but retained by the issuer (<sup>7</sup>).

#### 4. Valuation

For debt securities and listed shares, CSEC aggregate statistics are compiled at market value. For debt securities only, CSEC aggregate statistics are also compiled at face value and for stocks of debt securities at nominal value. The table below summarises the valuation methods used for compiling CSEC aggregate statistics:

Type of instrument	Stocks and flows at market value	Stocks and flows at face value	Stocks at nominal value
Debt securities	$\checkmark$	$\checkmark$	$\checkmark$
Listed shares	$\checkmark$	N/A	N/A

### 5. Overview of breakdowns

For the issuances of each individual euro area Member State, and of the euro area as a whole, CSEC aggregate statistics are measured in euro and compiled in accordance with the breakdowns defined in the following tables. The sector codes used in the tables have the meanings defined in Section 1 on 'Coverage and classifications'.

<sup>(7)</sup> See footnote 4.

22.6.2022

## Table A1

# Debt securities hierarchy 1 - Main maturity and interest rate type breakdowns for individual euro area Member States and the euro area as a whole

	Sector																				
	Currency of denomination, maturity, in Currency denomination, maturity, ins																				
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types																			
A.I.		All interest rate types																			
All currencies		Fixed coupon																			
	Long-term at original maturity	Zero coupon																			
		Variable interest rate																			
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
EUR		All interest rate types																			
EUR		Fixed coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
	Long-term at original maturity	Zero coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
		Variable interest rate		L		L	L			L		L	L	L	L	L		L	L	L	L
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
Other		All interest rate types																			
currencies		Fixed coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
	Long-term at original maturity	Zero coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L*
		Variable interest rate		L		L	L			L		L	L	L	L	L		L	L	L	L

Notes: Each cell of the table must be compiled for stocks, gross issuances, redemptions, revaluations and other changes in volume at market and face value as well as for stocks at nominal value. Cells marked as 'L' are lowest-level aggregates that cannot be broken down any further at the level of individual euro area Member States. Cells marked as 'L' are lowest-level aggregates used to identify CSEC priority series, which are subject to the data quality management (DQM) for CSEC aggregate statistics in this Annex. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

Notes: Each cell of the table must be compiled for stocks, gross issuances, redemptions, revaluations and other changes in volume at market and face value as well as for stocks at nominal value. Cells marked as 'L' are lowest-level aggregates that cannot be broken down any further at the level of individual euro area Member States. Cells marked as 'L' are lowest-level aggregates used to identify CSEC priority series, which are subject to the DQM for CSEC aggregate statistics in this Annex. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

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Inflation-linked variable rate

Interest rate-linked variable rate

Asset price-linked variable rate All interest rate types Fixed interest rate Fixed coupon

Zero coupon

Inflation-linked variable rate

Interest rate-linked variable rate Asset price-linked variable rate

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		Sec	ctor																			
(	Currency of denom	nination	, maturity, instrument type																			
Currency of denomination	Maturity		Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
			All interest rate types																			
			Fixed interest rate																			
			Fixed coupon																			
	All maturities		Zero coupon																			
All currencies	Air maturities		Variable interest rate																			
			Inflation-linked variable rate																			
			Interest rate-linked variable rate																			
			Asset price-linked variable rate																			
			All interest rate types																			
			Fixed interest rate																			
			Fixed coupon		L		L	L			L		L	L	L	L	L		L	L	L	L
			Zero coupon		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	All maturities		Variable interest rate																			
	1	I I																				

## Debt securities hierarchy 2 - Detailed interest rate type breakdowns for individual euro area Member States and the euro area as a whole

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## Debt securities hierarchy 3 – Detailed original maturity breakdowns for individual euro area Member States and the euro area as a whole

	Sector							1											1	1	
	Currency of denomination, maturity, instrument	type																			
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types																			
All currencies	Original maturity > 1 year and ≤ 2 years	All interest rate types																			
All currencies	Original maturity > 2 years and $\leq$ 5 years	All interest rate types																			
	Original maturity > 5 years and ≤ 10 years	All interest rate types																			
	Original maturity > 10 years	All interest rate types																			
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	Original maturity > 1 year and $\leq$ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	Original maturity > 2 years and $\leq$ 5 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 5 years and ≤ 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
Other	Original maturity > 1 year and $\leq$ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
currencies	Original maturity > 2 years and ≤ 5 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 5 years and $\leq$ 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L

Notes: Each cell of the table must be compiled for stocks, gross issuances, redemptions, revaluations and other changes in volume at market and face value as well as for stocks at nominal value. Cells marked as 'L' are lowest-level aggregates that cannot be broken down any further at the level of individual euro area Member States. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

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# Debt securities hierarchy 4 – Detailed residual maturity breakdowns for individual euro area Member States and the euro area as a whole

	Sector																				
	Currency of denomination, maturity, instrument	type	-																		
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
All currencies	Long-term original maturity with residual maturity ≤ 1 year	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 1 year and ≤ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	Long-term original maturity with residual maturity ≤ 1 year	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 1 year and ≤ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
Other currencies	Long-term original maturity with residual maturity ≤ 1 year	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 1 year and ≤ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L

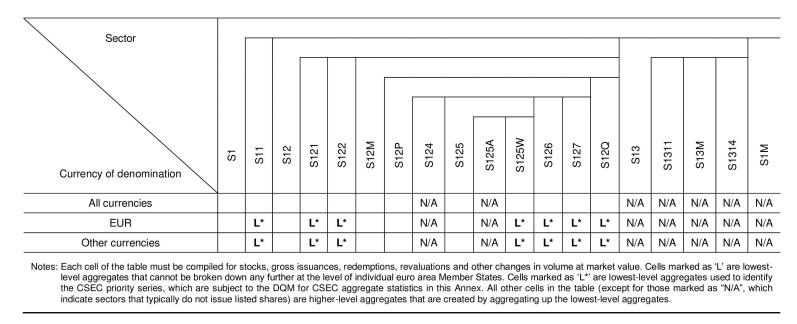
Notes: Each cell of the table must be compiled for stocks, gross issuances, redemptions, revaluations and other changes in volume at market and face value as well as for stocks at nominal value. Cells marked as 'L' are lowest-level aggregates that cannot be broken down any further at the level of individual euro area Member States. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

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Table A5

### Listed shares breakdowns for individual euro area Member States and the euro area as a whole



For the debt securities issuances of the non-euro area rest of the world, CSEC aggregate statistics must be measured in euro and be compiled in accordance with the breakdowns defined in the following tables. The sector codes used in the tables have the meanings defined in Section 1 on 'Coverage and classifications'.

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Table A6

# Debt securities hierarchy 1 - Main maturity and interest rate type breakdowns for the non-euro area rest of the world

	Sector																				
	Currency of denomination, maturity, in	nstrument type																			
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	100
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	
		All interest rate types																			
EUR		Fixed coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	
	Long-term at original maturity	Zero coupon		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	
		Variable interest rate		L		L	L			L		L	L	Ĺ	L	L		L	L	L	

level aggregates that cannot be broken down any further at the level of the non-euro area rest of the world. Cells marked as 'L\*' are lowest-level aggregates used to identify CSEC priority series, which are subject to the DQM for CSEC aggregate statistics in this Annex. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

Table A7

# Debt securities hierarchy 2 - Detailed interest rate type breakdowns for the non-euro area rest of the world

		Sec	tor																			
(	Currency of denom	ination,	maturity, instrument type	_																		
Currency of enomination	Maturity		Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
			All interest rate types																			
			Fixed interest rate																			
			Fixed coupon		L		L	L			L		L	L	L	L	L		L	L	L	L
			Zero coupon		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	All maturities		Variable interest rate																			
			Inflation-linked variable rate		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	Ľ
			Interest rate-linked variable rate		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L
			Asset price-linked variable rate		L*		L*	L*			L*		L*	L*	L*	L*	L*		L*	L*	L*	L

Notes: Each cell of the table must be compiled for stocks, gross issuances, redemptions, revaluations and other changes in volume at market and face value as well as for stocks at nominal value. Cells marked as 'L' are lowest-level aggregates that cannot be broken down any further at the level of the non-euro area rest of the world. Cells marked as 'L' are lowest-level aggregates used to identify CSEC priority series, which are subject to the DQM for CSEC aggregate statistics in this Annex. All other cells in the table are higher-level aggregates that are created by aggregating up the lowest-level aggregates.

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Table A8

# Debt securities hierarchy 3 - Detailed original maturity breakdowns for the non-euro area rest of the world

	Sector																				1
	Currency of denomination, maturity, instrument	type																			
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	Original maturity > 1 year and $\leq$ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
LUN	Original maturity > 2 years and ≤ 5 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 5 years and $\leq$ 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Original maturity > 10 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L

### Table A9

## Debt securities hierarchy 4 - Detailed residual maturity breakdowns for the non-euro area rest of the world

	Sector																				_
	Currency of denomination, maturity, instrument	type																			
Currency of denomination	Maturity	Instrument type	S1	S11	S12	S121	S122	S12M	S12P	S124	S125	S125A	S125W	S126	S127	S12Q	S13	S1311	S13M	S1314	S1M
	All maturities	All interest rate types																			
	Short-term at original maturity	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
EUR	Long-term original maturity with residual maturity ≤ 1 year	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 1 year and ≤ 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L
	Long-term original maturity with residual maturity > 2 years	All interest rate types		L		L	L			L		L	L	L	L	L		L	L	L	L

## euro

### 6. Compilation process for CSEC aggregate statistics

CSEC aggregate statistics are centrally and automatically compiled based on the item-by-item data included in the CSDB. The compilation process produces the lowest-level aggregates indicated in Tables A1 to A9 (cells identified with the letter 'L' or 'L\*'). All other aggregates defined in Tables A1 to A9 are produced by further aggregating up these lowest-level aggregates.

#### 7. Verification and DQM of CSEC aggregate statistics

The ECB will use its best efforts to compile and make available the CSEC aggregate statistics on a daily basis to enable the regular verification of the aggregates.

#### Verification of initial and regular aggregates

In accordance with the timetable in Table 2 of Annex II to this Guideline, the ECB and the NCBs must verify the initial and regular CSEC aggregate statistics by the end of the seventh working day of the calendar month following the reference month of the current production round to ensure that all sets of CSEC priority series have been verified.

The ECB and NCBs must use their best efforts in verifying the initial CSEC aggregate statistics based on information that is readily available to them and must examine the respective aggregates for their plausibility. Initial CSEC aggregate statistics must be flagged as 'provisional values' in the disseminated data.

The ECB and NCBs must thoroughly verify the regular CSEC aggregate statistics based on all currently available information including other benchmark data available outside the CSDB. Regular CSEC aggregate statistics must be flagged as 'normal values' in the disseminated data.

#### Prioritisation of verification work

In order to ensure an efficient verification workflow and to avoid duplication of verification work, the verification of CSEC aggregate statistics must focus on the 'CSEC priority series', i.e. the most relevant lowest-level CSEC aggregate statistics. Verifying the priority series will ensure that all higher-level aggregates that are based on these series, and to a significant extent also any related overlapping aggregates, are verified as well.

CSEC priority series represent the most relevant CSEC aggregate statistics for a country as measured by their outstanding amounts expressed as a share of amounts outstanding to the CSEC total economy aggregates for debt securities and as measured by their market capitalisation expressed as a share of market capitalisation to the CSEC total economy aggregates for listed shares. Priority series are defined as those lowest-level CSEC aggregate statistics for stocks at market value that are required to reach the Target 2 DQM threshold for that country.

For debt securities, CSEC aggregate statistics cover four overlapping hierarchies as defined in Tables A1 to A4 and A6 to A9. In order to avoid duplication of work, the identification of CSEC priority series for debt securities is based on the lowest-level 'short-term at original maturity' aggregates and 'long-term at original maturity' aggregates for 'fixed coupon' and 'zero coupon' as defined in Tables A1 and A6, as well as the lowest-level 'inflation-linked variable rate', 'interest rate-linked variable rate' and 'asset price-linked variable rate' aggregates as defined in Tables A2 and A7. This ensures a detailed verification of the breakdowns by instrument type as well as a high-level verification of the breakdowns by maturity (i.e. short-term vs. long-term at original maturity).

For listed shares, the identification of CSEC priority series is based on the lowest-level aggregates defined in Table A5.

The CSEC aggregate statistics must be verified at the level of 'sets of series', consisting of the related aggregates for the three valuation methods (i.e. market, nominal, and face value) and the five series types (i.e. stocks, gross issuances, redemptions, revaluations, and other changes in volume), which share the remaining breakdowns. This means that the verification of CSEC priority series must always cover the full set of series related to the respective CSEC priority series ('sets of CSEC priority series') for stocks at market value.

If sets of CSEC priority series exhibit a significant change in total outstanding amounts or market capitalisation after they have been verified but before the deadline for verification as defined by the timetable in Table 2 of Annex II to this Guideline, the CSDB must highlight the respective sets of series and the respective sets of series must be verified again.

#### DQM of CSEC aggregate statistics

In verifying and confirming the CSEC priority series, the ECB and NCBs must examine the time-series of the related sets of series for the following possible data quality issues:

- Outliers, i.e. values that differ significantly from the other values of the respective time-series;
- Stock-flow inconsistencies, i.e. reference periods during which current stocks do not equal the sum of previous stocks plus gross issuances minus redemptions plus revaluations, which could either be due to other changes in volume or data quality issues.

If the ECB and NCBs identify relevant statistical data quality issues during the verification of the initial and regular CSEC aggregate statistics, they must correct these issues in the underlying CSDB item-by-item data in due course but no later than the deadline specified in the timetable in Table 2 of Annex II to this Guideline. Corrections of the underlying item-by-item data will be reflected in the CSEC aggregate statistics that are compiled in the overnight processing for the following day.

# ANNEX V

# **CORRELATION TABLE**

Guideline 2012/689/EU (ECB/2012/21)	Guideline (EU) 2021/834 (ECB/2021/15)	This Guideline
Article 1	_	Article 1
Article 2	_	Article 2
_	_	Article 3(1)
Article 3(1)	_	Article 3(2)
Article 3(2)	-	Article 3(3)
_	-	Article 4(1), (2), (3) and (4)
Article 8	-	Article 4(5)
_	-	Article 4(6) and (7)
Article 4(1)	_	Article 5(1)
Article 4(2), Article 5(1) and (2), and Article 6(1)	_	Article 5(2)
Article 4(3)	_	Article 5(3)
Article 5(4)	_	Article 5(4)
_	_	Article 5(5)
Article 5(6) and Article 6(3)	_	Article 5(6)
Article 5(4)	_	Article 6(1)
Article 5(3)	_	Article 6(2)
Article 5(5)	_	Article 6(3)
Article 6(2)	_	Article 7
Article 5(4) and Article 6(2)	_	Article 8
Article 7(1)	_	Article 9(1)
Article 7(2)	-	Article 9(2)
_	-	Article 9(3)
_	-	Article 10
_	-	Article 11
	Article 9	Article 12

Guideline 2012/689/EU (ECB/2012/21)	Guideline (EU) 2021/834 (ECB/2021/15)	This Guideline
_	Article 5	Article 13
Article 10	Article 10	Article 14
_	_	Article 15
Article 11	Article 11	Article 16
Article 12	Article 12	Article 17
_	_	Annex I
Annex I	_	Annex II
Annex II	—	Annex III
_	_	Annex IV

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