

Official Journal of the European Union

L 133



English edition

Legislation

Volume 63

28 April 2020

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2020/578 of 21 February 2020 amending Regulation (EU) 2018/196 of the European Parliament and of the Council on additional customs duties on imports of certain products originating in the United States of America** 1
- ★ **Commission Implementing Regulation (EU) 2020/579 of 27 April 2020 granting a Union authorisation for the biocidal product family ‘HYPRED’s octanoic acid based products’ ⁽¹⁾** 4
- ★ **Commission Implementing Regulation (EU) 2020/580 of 27 April 2020 granting a Union authorisation for the biocidal product family ‘SOPURCLEAN’ ⁽¹⁾** 23
- ★ **Commission Implementing Regulation (EU) 2020/581 of 27 April 2020 amending Implementing Regulation (EU) 2018/659 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae ⁽¹⁾** 52

⁽¹⁾ Text with EEA relevance.

EN

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.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/578

of 21 February 2020

amending Regulation (EU) 2018/196 of the European Parliament and of the Council on additional customs duties on imports of certain products originating in the United States of America

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/196 of the European Parliament and of the Council of 7 February 2018 on additional customs duties on imports of certain products originating in the United States of America ⁽¹⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) As a result of the United States' failure to bring the Continued Dumping and Subsidy Offset Act (CDSOA) in compliance with its obligations under the World Trade Organization (WTO) agreements, Regulation (EU) 2018/196 originally imposed a 4,3 % *ad valorem* additional customs duty on imports of certain products originating in the United States of America. In conformity with the WTO authorisation to suspend the application of concessions to the United States, the Commission is to adjust the level of suspension annually to the level of nullification or impairment caused by the CDSOA to the European Union at that time. In 2019, the level of suspension was adjusted to 0,001 % *ad valorem* additional customs duty and Regulation (EU) 2018/196 was amended accordingly.
- (2) The CDSOA disbursements for the most recent year for which data are available relate to the distribution of anti-dumping and countervailing duties collected during the Fiscal Year 2019 (1 October 2018-30 September 2019). On the basis of the data published by the United States' Customs and Border Protection and pursuant to Article 3(1)(a) of Regulation (EU) 2018/196, the level of nullification or impairment caused to the Union is calculated at USD 25 506,30.
- (3) The level of nullification or impairment and consequently of suspension has increased compared to the 2019 level. However, the level of suspension cannot be adjusted to the level of nullification or impairment in accordance with Article 3(1)(c) by adding products to the list in Annex I to Regulation (EU) 2018/196, as all products from the list in Annex II to Regulation (EU) 2018/196 have already been added to Annex I. As a consequence, in accordance with Article 3(1)(e) of that Regulation, the Commission should keep the list of products in Annex I unchanged and amend the rate of the additional duty in order to adjust the level of suspension to the level of nullification or impairment. The four products listed in Annex I should therefore be maintained on the list and the rate of additional import duty should be amended and set at 0,012 %.
- (4) The effect of a 0,012 % *ad valorem* additional import duty on imports from the United States of the products in Annex I represents, over one year, a value of trade that does not exceed USD 25 506,30.
- (5) To make sure that there are no delays in the application of the amended rate of additional import duty, this Regulation should enter into force on the day of its publication.

⁽¹⁾ OJ L 44, 16.2.2018, p. 1.

(6) Regulation (EU) 2018/196 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 2 of Regulation (EU) 2018/196 is replaced by the following:

‘Article 2

An *ad valorem* duty of 0,012 % additional to the customs duty applicable under Regulation (EU) No 952/2013 of the European Parliament and of the Council (*) shall be imposed on the products originating in the United States listed in Annex I to this Regulation.

(*) OJ L 269, 10.10.2013, p. 1.’

Article 2

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

It shall apply from 1 May 2020.

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

Done at Brussels, 21 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

‘ANNEX I

The products on which additional import duties are to apply are identified by their eight-digit CN codes. The description of products classified under these codes can be found in Annex I to Council Regulation (EEC) No 2658/87 ⁽¹⁾.

0710 40 00

ex 9003 19 00 “frames and mountings of base metal”

8705 10 00

6204 62 31

⁽¹⁾ Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).’

COMMISSION IMPLEMENTING REGULATION (EU) 2020/579**of 27 April 2020****granting a Union authorisation for the biocidal product family 'HYPRED's octanoic acid based products'****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 25 August 2015, HYPRED SAS, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'HYPRED's octanoic acid based products' of product-type 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under the case number BC-LR019297-17 in the Register for Biocidal Products.
- (2) 'HYPRED's octanoic acid based products' contains octanoic 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 19 December 2017, 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 11 July 2019, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics ('SPC') of 'HYPRED's octanoic acid based products' 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 'HYPRED's octanoic acid based products' is a 'biocidal product family' within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 25 July 2019, 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 'HYPRED's octanoic acid based products'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0021020-0000 is granted to HYPRED SAS for the making available on the market and use of the biocidal product family 'HYPRED's octanoic acid based products' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 May 2020 until 30 April 2030.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 26 June 2019 on the Union authorisation of 'HYPRED's octanoic acid based products' (ECHA/BPC/226/2019), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

Article 2

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

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

Done at Brussels, 27 April 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's octanoic acid based products

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0021020-0000

R4BP asset number: EU-0021020-0000

PART I

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

Name	HYPRED's octanoic acid based products
------	---------------------------------------

1.2. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

1.3. Authorisation holder

Name and address of the authorisation holder	Name	HYPRED SAS
	Address	55 boulevard Jules Verger, 35803 DINARD, France
Authorisation number	EU-0021020-0000	
<i>R4BP asset number</i>	EU-0021020-0000	
Date of the authorisation	18 May 2020	
Expiry date of the authorisation	30 April 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	HYPRED SAS
Address of manufacturer	55 Boulevard Jules Verger, 35803 DINARD France
Location of manufacturing sites	HYPRED SAS – 55 Boulevard Jules Verger – BP 10180, 35803 DINARD France HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4, 64320 buk Poland HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C n° 32, 31160 Orcoyen – NAVARRA Spain HYPRED GmbH Marie-Curie-Straße 23, 53332 Bornheim – Sechtem Germany HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova, 26010 Ripalta Arpina CR Italy AG France S.A.S – Zone Industrielle Le Roineau, 72500 Vaas France Anti-Germ Austria GmbH – 'Pfongauer Straße 17, 5202 Neumarkt am Wallersee' Austria Anti-Germ Deutschland GmbH – Oberbrühlstraße 16-18, 87700 Memmingen Germany

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

Active substance	Octanoic acid
Name of manufacturer	Emery Oleochemicals (M)
Address of manufacturer	Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia
Location of manufacturing sites	Sdn Bhd (63112-D), Lot 4, Jalan Perak, Kawasan Perusahaan, 42500 Telok Panglima Garang, Selangor Malaysia

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0	10,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	21,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	17,6
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	2,25	6,0
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	0,0	15,0

2.2. **Type(s) of formulation**

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

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

Identifier	Meta SPC 1
------------	------------

1.2. **Suffix to the authorisation number**

Number	1-1
--------	-----

1.3. **Product type(s)**

Product type(s)	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
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0	3,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	21,0	21,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	2,25	2,25
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5,0	5,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment.

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

4.1. Use description

Table 1. Use # 1 – Circulation in dairy industry

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

Field(s) of use	Indoor Cleaning – disinfection of circuits in dairy industry
Application method(s)	Closed system: Circulation Clean-in-place (CIP), circulation
Application rate(s) and frequency	- Use 1 % product solution for bactericidal activity and 1,5 % product solution for yeasticidal activity 1 to 3 cycles per day, 208 to 360 days per year
Category(ies) of users	Professional
Pack sizes and packaging material	Opaque jerrycan High-density polyethylene (HDPE) 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L

4.1.1. *Use-specific instructions for use*

Rinse the circuits with drinking water before disinfection.

Apply the product by circulation.

Product concentration and contact time:

— 1 % bactericidal in 5 minutes

— 1,5 % yeasticidal in 15 minutes

Temperature of the product solution: 40 – 85 °C

Rinse with drinking water.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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

See general directions for use

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

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 – Circulation in farms

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

Field(s) of use	Indoor Cleaning – disinfection of milking equipment and milking robots in farms
Application method(s)	Closed system: Circulation
Application rate(s) and frequency	- Use 0,8 % product solution for bactericidal activity and 1,5 % product solution for yeasticidal activity. The milk installations cleaned and disinfected twice a day and the milk tank is cleaned and disinfected once every three days.
Category(ies) of users	Professional
Pack sizes and packaging material	Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L

4.2.1. *Use-specific instructions for use*

Milk installations with or without a programmer.

- (1) After milking, rinse the equipment with warm drinking water.
- (2) Apply the solution by circulation at an initial recommended temperature of 60 °C minimum to achieve a final temperature of 40– 45 °C.

Product concentration and contact time:

0,8 % bactericidal in 10 minutes

1,5 % yeasticidal in 15 minutes

Do not use at temperature above 75 °C.

- 3) Rinse with cold drinking water.

Use the product twice a day or once a day when alternating with another product.

When alternating, use an alternative cleaner-disinfectant or a cleaning product 1 to 4 times per week depending on the temperature reached in the system.

Contact your supplier for choosing the alternative product and the frequency of use.

Do not mix the product with an alkaline or chlorinated alkaline product.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

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

See general directions for use

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

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

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

5.1. Instructions for use

See use specific instructions for use.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

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

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

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

The cleaning properties of the product has not been assessed as they are not covered by Regulation (EU) No 528/2012.

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

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)	HYPRACID ONE DEPTACID BD prevides®MS				
Authorisation number	EU-0021020-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	21,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	2,25
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5,0

META SPC 21. **META SPC 2 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC 2
------------	------------

1.2. **Suffix to the authorisation number**

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

1.3. **Product type(s)**

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	10,0	10,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	14,0	14,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	4,5	4,5
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	15,0	15,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment.

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

4.1. Use description

Table 3. Use # 1 – Circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of circuits in breweries, dairy and beverage industries
Application method(s)	Closed system: Circulation CIP, circulation
Application rate(s) and frequency	- Use 0,4 % product solution for bactericidal activity and 0,6 % product solution for yeasticidal activity. 1 to 3 cycles per day, 208 to 360 days per year
Category(ies) of users	Professional
Pack sizes and packaging material	Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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

See general directions for use

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

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

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

5.1. **Instructions for use**

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply the product by circulation.

Product concentration and contact time:

— 0,4 % bactericidal in 5 minutes

— 0,6 % yeastocidal in 15 minutes

Temperature of the product solution: 20 – 85 °C

Rinse with drinking water.

5.2. **Risk mitigation measures**

— Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).

— Ensure adequate ventilation during the application.

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

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

FIRST AID

— IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.

— IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.

— IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

— IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number.

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

(*) 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.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Keep in a cool place. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

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

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

Trade name(s)	DEPTACID CCB				
Authorisation number	EU-0021020-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	10,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	14,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	4,5
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	15,0

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3
------------	------------

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

2. META SPC 3 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	10,0	10,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	0,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	17,6	17,6
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	6,0	6,0
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	0,0	0,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment.

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

4.1. Use description

Table 4. Use # 1 – Circulation

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

Field(s) of use	Indoor Disinfection of circuits in breweries, dairy and beverage industries
Application method(s)	Closed system: Circulation CIP, circulation
Application rate(s) and frequency	- Use 0,4 % product solution 1 to 3 cycles per day, 208 to 360 days per year
Category(ies) of users	Professional
Pack sizes and packaging material	Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L

4.1.1. *Use-specific instructions for use*

See general directions for use

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

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

See general directions for use

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

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

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

5.1. **Instructions for use**

Prior to the application of the product, clean with a detergent and rinse with drinking water.

Apply the product by circulation.

Product concentration: 0,4 %

Contact time:

— 5 minutes for bactericidal activity

— 15 minutes for yeasticidal activity

Temperature of the product solution: 20 – 85 °C

Rinse with drinking water.

5.2. **Risk mitigation measures**

— Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).

— Ensure adequate ventilation during the application.

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

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

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

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number.

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf-life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	DEPTACID CB				
Authorisation number	EU-0021020-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	10,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	17,6
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	6,0

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	Meta SPC 4
------------	------------

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

2. META SPC 4 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0	3,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	21,0	21,0
L-(+)-Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	3,0	3,0
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5,0	5,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. 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. Dispose of contents according to local/regional/national/international regulation. Avoid release to the environment.

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

4.1. Use description

Table 5. Use # 1 – Separative membranes circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfectant or cleaner-disinfectant for membranes used in reverse osmosis and nanofiltration in dairy and beverage industries.
Application method(s)	Closed system: Circulation
Application rate(s) and frequency	— Use 0,75 % product solution if cleaning is applied prior to the disinfection — Use 1 % product solution if no cleaning is applied prior to the disinfection 1 to 3 cycles per day, 104 to 312 days per year
Category(ies) of users	Professional
Pack sizes and packaging material	Opaque jerrycan HDPE 5L Opaque jerrycan HDPE 10L Opaque jerrycan HDPE 22L Opaque drum HDPE 60L Opaque drum HDPE 120L Opaque drum HDPE 220L Opaque container HDPE 640L Opaque container HDPE 1000L

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

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

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

5.1. Instructions for use

Rinse the membranes with drinking water or clean and rinse with drinking water before disinfection.

^(*) 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.

Apply the product by circulation

Product concentration if no cleaning is applied prior to the disinfection: 1 %

Product concentration if cleaning is applied prior to the disinfection: 0,75 %

Contact time:

— 5 minutes for bactericidal activity

— 15 minutes for yeasticidal activity

Temperature of the product solution: 40 – 85 °C

Rinse with drinking water.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves, coverall and eye protection during product handling phase (protective material to be specified by the authorisation holder in the product information).
- Ensure adequate ventilation during the application.

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

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

FIRST AID

- IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/physician.
- IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.
- IF IN EYES: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
- IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.

See Safety Data Sheets. They contain an emergency phone number

When asking for medical advice keep packaging or label at hand and call a POISON CENTER or doctor/physician.

NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.

NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

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

Do not discharge the product directly to sewer or to the environment.

Dispose the product and its packaging in accordance with applicable local and national regulations.

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

Shelf life: 2 years in HDPE

Conditions of storage: keep only in the original packaging. Keep container closed. Do not store at temperature above 40 °C.

6. OTHER INFORMATION

The cleaning properties of the product has not been assessed as they are not covered by Regulation (EU) No 528/2012.

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)	DEPTACID WCM				
Authorisation number	EU-0021020-0004 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	3,0
Methanesulfonic acid		Non-active substance	75-75-2	200-898-6	21,0
N,N-dimethyl-1-Decanamine, N-oxid		Non-active substance	2605-79-0	220-020-5	3,0
Ethoxylated alcohol	Ethoxylated alcohol	Non-active substance	31726-34-8	500-077-5	5,0

COMMISSION IMPLEMENTING REGULATION (EU) 2020/580
of 27 April 2020
granting a Union authorisation for the biocidal product family ‘SOPURCLEAN’
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 28 August 2015, 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 ‘SOPURCLEAN’ of product-type 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 the case number BC-PJ019489-22 in the Register for Biocidal Products.
- (2) ‘SOPURCLEAN’ contains octanoic acid and decanoic acid, as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 15 December 2017, 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 15 July 2019, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘SOPURCLEAN’ 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 ‘SOPURCLEAN’ is a ‘biocidal product family’ within the meaning of Article 3(1)(s) of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (6) On 26 July 2019, 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 ‘SOPURCLEAN’.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0021157-0000 is granted to SOPURA N.V. for the making available on the market and use of the biocidal product family ‘SOPURCLEAN’ in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 18 May 2020 until 30 April 2030.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 26 June 2019 on the Union authorisation of ‘SOPURCLEAN’ (ECHA/BPC/227/2019), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

Article 2

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

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

Done at Brussels, 27 April 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

SOPURCLEAN

Product type 4 – Food and feed area (Disinfectants)

Authorisation number: EU-0021157-0000

R4BP asset number: EU-0021157-0000

PART I

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

Name	SOPURCLEAN
------	------------

1.2. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

1.3. Authorisation holder

Name and address of the authorisation holder	Name	SOPURA N.V.
	Address	Rue de Trazegnies 199, 6180 COURCELLES, Belgium
Authorisation number	EU-0021157-0000	
R4BP asset number	EU-0021157-0000	
Date of the authorisation	18 May 2020	
Expiry date of the authorisation	30 April 2030	

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	PIB de Tyberchamps 14, 7180 SENEFFE Belgium Rue de Trazegnies 199, 6180 COURCELLES Belgium

Name of manufacturer	SOPURA QUIMICA
Address of manufacturer	Poligon 'La Canaleta',AVINGUDA JÚPITER 9, 25300 TARREGA Spain
Location of manufacturing sites	Poligon 'La Canaleta',AVINGUDA JÚPITER 9, 25300 TARREGA Spain

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

Active substance	Octanoic acid
Name of manufacturer	Emery Oleochemicals (M) Sdn Bhd (63112-D)
Address of manufacturer	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 Selangor Malaysia
Location of manufacturing sites	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 Selangor Malaysia

Active substance	Decanoic acid
Name of manufacturer	Emery Oleochemicals (M) Sdn Bhd (63112-D)
Address of manufacturer	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 Selangor Malaysia
Location of manufacturing sites	Lot 4, Jalan Perak, Kawasan Perusahaan, Telok Panglima Garang, 42500 Selangor Malaysia

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	1,1	2,7
Decanoic acid		Active Substance	334-48-5	206-376-4	0,3	1,5
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,0	31,2
Propionic acid		Non-active substance	79-09-4	201-176-3	0,0	19,5
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	0,0	30,0
Nitric acid		Non-active substance	7697-37-2	231-714-2	0,0	18,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	20,3
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	4,2
Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	35,2
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	3,0

2.2. **Type(s) of formulation**

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

Identifier	Meta SPC 1
------------	------------

1.2. Suffix to the authorisation number

Number	1-1
--------	-----

1.3. Product type(s)

Product type(s)	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
Octanoic acid		Active Substance	124-07-2	204-677-5	1,1	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	0,75	1,5
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,0	31,2
Propionic acid		Non-active substance	79-09-4	201-176-3	0,0	0,0
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	0,0	30,0
Nitric acid		Non-active substance	7697-37-2	231-714-2	0,0	0,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	12,6
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	4,2
Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	3,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage.
Precautionary statements	Do not breathe vapours. 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. Immediately call a doctor. Wear eye protection. Wear face protection. Wear protective clothing. Wear protective gloves. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water (or shower). Keep only in original container. Store in a well-ventilated place. Keep container tightly closed. Absorb spillage to prevent material damage. Dispose of contents in accordance with local/regional/national/international regulations.

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

4.1. Use description

Table 1

Use # 1 – Cleaning in place (CIP) with circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Closed system For disinfection of pipes, tanks, and other parts of the closed system: — Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) — Circulation in a closed CIP system
Application rate(s) and frequency	— For an effect on bacteria and yeasts: Dilution rate: 1,5 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 2 % v/v. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -

Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	• Jerrycan High-density polyethylene (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*). • Intermediate bulk containers (IBC, PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.
(*) Depending on biocidal product specific weight.	

4.1.1. Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

4.1.2. Use-specific risk mitigation measures

During the mixing, loading and application phases:

- Transfer in closed systems and industrial risk mitigation measures (RMM) excluding risk for skin and eye exposure (containers containing the product are connected to CIP via installed pipes; connections with dry coupling).
- Treated equipment (vessels) and dosing equipment has to be rinsed with drinking water after use.

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

See general directions for use.

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

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 – Dipping/soaking

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Open system: immersion For disinfection of small hard non-porous parts (e.g. spare parts, tools, valves, hoses) used in the food manufacturing process: — Concentrated product pumped in the bath and tap water added to reach the required concentration — Immersion

Application rate(s) and frequency	— For an effect on bacteria and on yeasts: Dilution rate: 1,5 %v/v In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 2 % v/v. Contact time: minimum 15 minutes at +4 °C and above, up to 20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*). • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.
(*) Depending on biocidal product specific weight.	

4.2.1. Use-specific instructions for use

The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

4.2.2. Use-specific risk mitigation measures

During the post application phase:

Rinse the equipment with drinking water.

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.

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

5.1. Instructions for use

For an effect on bacteria and on yeasts

- Rinsing and cleaning before disinfection:

Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users). For disinfection procedures in slaughterhouses, cleaning with a cold alkaline solution) is mandatory before disinfection.

- Disinfecting cycle:

— Dilution of the concentrated product in tap water before use: 1,5 %

In case of outbreaks of *Pediococcus damnosus*, the product must be used at 2 %.

— Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C.

- Final rinsing with drinking water

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

5.2. Risk mitigation measures

Use in well-ventilated places.

During the mixing, loading and application phases: wear a protective coverall. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Use eye protection during handling of the product. Wear face protection.

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

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. Absence of visual oral burns does not exclude esophageal burns.
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure: Seek medical attention immediately. ALWAYS check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. Keep a bottle of water at hand.
- In case of skin contact: Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. NO scrubbing.
- In case of mouth contact or ingestion: Do NOT induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion consider performing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER

Emergency measures to protect the environment:

- Prevent entry into sewers and public waters.
- Clean up any spills as soon as possible, using an absorbent material (e.g. earth, sand) to collect the spill. Use suitable disposal containers.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place

Keep the product away from direct sunlight, source of heat and ignition.

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

Do not discharge unused product on the ground, into water courses, into pipes (e.g. 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

Storage conditions:

- Store in a clean area allowing recuperation of leaks and effusion.
- Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep container closed when not in use.
- Handle in accordance with good industrial hygiene and safety procedures.

Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life: 12 months in the original packaging.

6. OTHER INFORMATION

Any product in meta SPC1 shall contain sufficient amounts of acids to yield a $\text{pH} \leq 2$ at the dilution of 1,5 %.

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)	SEPTACID BN				
Authorisation number	EU-0021157-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,5
Decanoic acid		Active Substance	334-48-5	206-376-4	1,5
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	31,2
Glycolic acid		Non-active substance	79-14-1	201-180-5	4,2

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

Trade name(s)	SEPTACID BN PS				
Authorisation number	EU-0021157-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,5
Decanoic acid		Active Substance	334-48-5	206-376-4	1,5
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	30,0
Glycolic acid		Non-active substance	79-14-1	201-180-5	4,2

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

Trade name(s)	SOPURCIP EC				
Authorisation number	EU-0021157-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,1
Decanoic acid		Active Substance	334-48-5	206-376-4	0,75
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	7,8
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	12,6

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

Trade name(s)	SOPURCLEAN BN				
Authorisation number	EU-0021157-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	29,64
Citric acid		Non-active substance	77-92-9	201-069-1	3,0

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

Trade name(s)	SOPURCLEAN BN PS				
Authorisation number	EU-0021157-0005 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	30,0
Citric acid		Non-active substance	77-92-9	201-069-1	2,5

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC 2
------------	------------

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	2,7	2,7
Decanoic acid		Active Substance	334-48-5	206-376-4	0,3	0,3
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,0	0,0
Propionic acid		Non-active substance	79-09-4	201-176-3	19,5	19,5
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	3,8	3,8
Nitric acid		Non-active substance	7697-37-2	231-714-2	0,0	0,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	0,0
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	0,0
Lactic acid		Non-active substance	79-33-4	201-196-2	35,2	35,2
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	0,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation.
Precautionary statements	Do not breathe vapours. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection.

	IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water (or shower). 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. Immediately call a doctor. Keep only in original container. Store in a well-ventilated place.Keep container tightly closed. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. Dispose of contents in accordance with local/regional/national/international regulations.
--	--

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

4.1. Use description

Table 3

Use # 1 – Cleaning in place (CIP) with circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Closed system For disinfection of pipes, tanks, and other parts of the closed system: — Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) — Circulation in a closed CIP system
Application rate(s) and frequency	- - For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v In case of outbreaks of <i>Pediococcus damnosus</i> , the product must be used at 1,5 % v/v. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*) • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.

(*) Depending on biocidal product specific weight.

4.1.1. *Use-specific instructions for use*

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

4.1.2. *Use-specific risk mitigation measures***During the mixing, loading and application phases:**

— Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure. IBC containers containing the product are connected to CIP via installed pipes; connections are made with dry coupling.

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 4

Use # 2 – Spraying

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Spraying For disinfection of hard non-porous surfaces in contact with food processing: — Diluted biocidal product sprayed via a low pressure spraying device
Application rate(s) and frequency	Maximum application rate: 100 mL/m ² – For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the product must be used at 1,5 %. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg. (*) • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.

(*) Depending on biocidal product specific weight.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Fully automated process where workers are not present during spraying.

Workers only re-enter in the work area when spraying solution has been drained.

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 5

Use # 3 – Manual disinfection

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor In food and feed areas
Application method(s)	Manual application For disinfection of hard non-porous small parts and surfaces used in the food manufacturing process: — Diluted product sprayed via a low pressure spraying device — After the optimal contact time for disinfection, the small parts are to be wiped or mopped or brushed.
Application rate(s) and frequency	Maximum application rate: 100 mL/m ² – For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 1,5 %. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*). • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.

(*) Depending on biocidal product specific weight.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See 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 6

Use # 4 – Dipping/soaking

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Open system: immersion For disinfection of hard non-porous small parts (e.g. spare parts, tools, valves, hoses) used in the food manufacturing process: — Concentrated product pumped in the bath and tap water added to reach the required concentration — Immersion
Application rate(s) and frequency	— For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 1,5 %. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). Jerrycan (PE-HD), containing: 20 to 25 kg (*). Drums (PE-HD) containing 200 to 250 kg (*). Containers (PE-HD) containing 600 to 750 kg (*). IBC (Internal bulk containers, PE-HD) containing 1 100 to 1 250 kg (*). Bulk delivery.

(*) Depending on biocidal product specific weight.

4.4.1. *Use-specific instructions for use*

The dipping solution must be replaced by a fresh solution when it becomes visually polluted, and in all cases daily.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See 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 ⁽²⁾ OF THE META SPC 2**

5.1. **Instructions for use**

For an effect on bacteria and on yeasts

- Rinsing and cleaning before disinfection: Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users).

For disinfection procedures in slaughterhouses, cleaning with a cold alkaline solution is mandatory before disinfection.

- Disinfecting cycle:
 - Dilution of the concentrated product in tap water before use: 1,0 %. In case of outbreaks of *Pediococcus damnosus*, the products must be used at 1,5 %.
 - Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C.
 - Disinfection via spraying/manual disinfection: Make sure to wet surfaces completely.
- Final rinsing: not necessary

5.2. **Risk mitigation measures**

During the mixing and loading and application phases: wear a protective coverall. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Use of eye protection during handling of the product. Wear face protection.

Use in well ventilated places.

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

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. Absence of visual oral burns does not exclude esophageal burns.
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

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

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure: Seek medical attention immediately. ALWAYS check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. Keep a bottle of water at hand.
- In case of skin contact: Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. NO scrubbing.
- In case of mouth contact or ingestion: Do NOT induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion consider performing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER

Emergency measures to protect the environment:

- Prevent entry into sewers and public waters.
- Clean up any spills as soon as possible, using an absorbent material (earth, sand, ...) to collect the spill. Use suitable disposal containers.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place

Keep the product away from direct sunlight, source of heat and ignition.

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

Do not discharge unused product on the ground, into water courses, into pipes (e.g. 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

Storage conditions:

- Store in a clean area allowing recuperation of leaks and effusion.
- Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep packaging closed when not in use.
- Handle in accordance with good industrial hygiene and safety procedures.

Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life: 12 months in the original packaging.

6. OTHER INFORMATION

-

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

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

Trade name(s)	SOPURCLEAN NR				
Authorisation number	EU-0021157-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	2,7
Decanoic acid		Active Substance	334-48-5	206-376-4	0,3
Propionic acid		Non-active substance	79-09-4	201-176-3	19,5
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	3,8
Lactic acid		Non-active substance	79-33-4	201-196-2	35,2

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3
------------	------------

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

2. META SPC 3 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2	1,2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	0,0	0,0
Propionic acid		Non-active substance	79-09-4	201-176-3	0,0	0,0
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	0,0	0,0
Nitric acid		Non-active substance	7697-37-2	231-714-2	18,0	18,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	0,0	0,0
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	0,0
Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	0,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Harmful if inhaled.
Precautionary statements	Do not breathe vapours. Wear protective clothing. Wear eye protection. Wear protective gloves. Wear face 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 doctor. Immediately call a POISON CENTER. Keep only in original container. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Store in a well-ventilated place. Keep container tightly closed. Absorb spillage to prevent material damage. Dispose of contents in accordance with local/regional/national/international regulations.

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

4.1. Use description

Table 7

Use # 1 – Cleaning in place (CIP) with circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Closed system For disinfection of pipes, tanks, and other parts of the closed system. — Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) — Circulation in a closed CIP system
Application rate(s) and frequency	— For an effect on bacteria and on yeasts: Dilution rate: 1,5 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 2 % v/v. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C. -
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*). • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.
(*) Depending on biocidal product specific weight.	

4.1.1. Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

4.1.2. Use-specific risk mitigation measures

During the mixing, loading and application phases:

- Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure. (Containers containing the product are connected to CIP via installed pipes; connections are made with dry coupling.

During the mixing and loading phases:

- Wear respiratory mask.

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.

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

5.1. **Instructions for use**

For an effect on bacteria and on yeasts

- Rinsing and cleaning before disinfection:

Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users).

For disinfection procedures in slaughterhouses, cleaning with a cold alkaline solution is mandatory before disinfection.

- Disinfecting cycle:
 - Dilution of the concentrated product in tap water before use: 1,5 %In case of outbreaks of *Pediococcus damnosus*, the product must be used at 2 %.
- Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C.
- Final rinsing with drinking water

5.2. **Risk mitigation measures**

Use in well-ventilated places.

During the mixing, loading and application phases:

Wear a protective coverall. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Use of eye protection during handling of the product. Wear face protection.

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

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. Absence of visual oral burns does not exclude esophageal burns.
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure: Seek medical attention immediately. ALWAYS check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand).
- In case of skin contact: Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. NO scrubbing.

^(*) 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.

- In case of mouth contact or ingestion: Do NOT induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion consider performing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER

Emergency measures to protect the environment:

- Prevent entry into sewers and public waters.
- Clean up any spills as soon as possible, using an absorbent material (e.g. earth, sand) to collect the spill. Use suitable disposal containers.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place

Keep the product away from direct sunlight, source of heat and ignition.

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

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**

Storage conditions:

- Store in a clean area allowing recuperation of leaks and effusion.
- Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep packaging closed when not in use.
- Handle in accordance with good industrial hygiene and safety procedures.

Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life: 12 months in the original packaging.

6. OTHER INFORMATION

-

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	SOPURCLEAN OP-N				
Authorisation number	EU-0021157-0007 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2
Nitric acid		Non-active substance	7697-37-2	231-714-2	18,0

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 4 identifier

Identifier	Meta SPC 4
------------	------------

1.2. Suffix to the authorisation number

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

1.3. Product type(s)

Product type(s)	PT04 – Food and feed area (Disinfectants)
-----------------	---

2. META SPC 4 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2	1,2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	4,68	4,68
Propionic acid		Non-active substance	79-09-4	201-176-3	0,0	0,0
Phosphoric acid		Non-active substance	7664-38-2	231-633-2	0,0	0,0
Nitric acid		Non-active substance	7697-37-2	231-714-2	0,0	0,0
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	20,3	20,3
Glycolic acid		Non-active substance	79-14-1	201-180-5	0,0	0,0
Lactic acid		Non-active substance	79-33-4	201-196-2	0,0	0,0
Citric acid		Non-active substance	77-92-9	201-069-1	0,0	0,0

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

Formulation(s)	SL – Soluble concentrate
----------------	--------------------------

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. May cause respiratory irritation.
Precautionary statements	Do not breathe vapours. Wear protective clothing. Wear eye protection. Wear protective gloves. Wear face 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. Immediately call a doctor. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. Keep only in original container. Store in a well-ventilated place.Keep container tightly closed. Absorb spillage to prevent material damage. Dispose of contents in accordance with local/regional/national/international regulations.

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

4.1. Use description

Table 8

Use # 1 – Cleaning in place (CIP) with circulation

Product type	PT04 – Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor In food and feed areas
Application method(s)	Closed system For disinfection of pipes, tanks, and other parts of the closed system. — Biocidal product (semi-)automatically dosed in the CIP vessel (either by volume or conductivity measurements) — Circulation in a closed CIP system
Application rate(s) and frequency	— For an effect on bacteria and on yeasts: Dilution rate: 1,5 %v/v. In case of outbreaks of <i>Pediococcus damnosus</i> , the products must be used at 2 %. Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C.
Category(ies) of users	Industrial Trained professional
Pack sizes and packaging material	• Jerrycan (PE-HD), containing: 10 to 12,5 kg (*). • Jerrycan (PE-HD), containing: 20 to 25 kg (*). • Drums (PE-HD) containing 200 to 250 kg (*). • Containers (PE-HD) containing 600 to 750 kg (*). • IBC (PE-HD) containing 1 100 to 1 250 kg (*) • Bulk delivery.
(*) Depending on biocidal product specific weight.	

4.1.1. Use-specific instructions for use

In case of re-use of the disinfectant solution for CIP procedures, the active substance concentration must be measured and restored to its intended level before re-use.

4.1.2. Use-specific risk mitigation measures

During the mixing, loading and application phase:

— Transfer in closed systems and industrial RMM excluding risk for skin and eye exposure, IBC containers containing the product are connected to CIP via installed pipes; connections are made with dry coupling.

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.

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

5.1. **Instructions for use**

For an effect on bacteria and on yeasts

- Rinsing and cleaning before disinfection:

Not mandatory (even if a pre-rinsing is always recommended and usually performed by the users).

For disinfection procedures in slaughterhouses, cleaning with a cold alkaline solution is mandatory before disinfection.

- Disinfecting cycle:

— Dilution of the concentrated product in tap water before use: 1,5 %

In case of outbreaks of *Pediococcus damnosus*, the products must be used at 2 %.

— Contact time: minimum 15 minutes at +4 °C and above, up to +20– 25 °C.

- Final rinsing with drinking water

5.2. **Risk mitigation measures**

Use in well-ventilated places.

During the mixing, loading and application phases:

Wear a protective coverall. Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information). Use eye protection during handling of the product. Wear face protection.

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

Particulars of likely direct or indirect adverse effects:

- Severe chemical burns and/or corrosion of the eyes, mucosae, respiratory and digestive tract with the risk of perforation and intense pain. Absence of visual oral burns does not exclude esophageal burns.
- If aspiration and/or ingestion occurs this may induce chemical pneumonia and metabolic acidosis.

First aid instructions:

- Relocate the individual from the exposure source and remove any contaminated/spattered clothing articles.
- In case of inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures.
- In case of eye exposure: Seek medical attention immediately. ALWAYS check for and remove contact lenses. Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand).

⁽⁴⁾ 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.

- In case of skin contact: Obtain medical attention. Remove contaminated clothing and shoes. Wash affected area with plenty of water. NO scrubbing.
- In case of mouth contact or ingestion: Do NOT induce vomiting, if the individual is conscious, able to swallow saliva without coughing and ingestion occurred in less than one hour proceed to mouth wash with plenty of water. Take to hospital.
- NEVER administer liquids/solids orally to an impaired or unconscious individual; place individual in left sideways position with the head lowered and the knees bent.
- Keep the individual calm and at rest, conserve body temperature and control breathing. If necessary check for pulse and initiate artificial respiration.
- If symptoms persist or worsen bring individual to a healthcare center, bring packaging or label whenever possible.
- NEVER LEAVE THE AFFECTED INDIVIDUAL UNATTENDED!

Advice for medical and healthcare personnel:

- In case of ingestion consider performing an endoscopic procedure.
- The use of ipecac syrup, neutralization and activated charcoal is not advised.
- Symptomatic and supportive treatment.
- WHEN ASKING FOR MEDICAL ADVICE KEEP PACKAGING OR LABEL AT HAND AND CALL YOUR LOCAL POISON CONTROL CENTER

Emergency measures to protect the environment:

- Prevent entry into sewers and public waters.
- Clean up any spills as soon as possible, using an absorbent material (e.g. earth, sand) to collect the spill. Use suitable disposal containers.

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

Keep only in the original packaging tightly closed in a cool and well-ventilated place

Keep the product away from direct sunlight, source of heat and ignition.

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

Do not discharge unused product on the ground, into water courses, into pipes (e.g. 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**

Storage conditions:

- Store in a clean area allowing recuperation of leaks and effusion.
- Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep packaging closed when not in use.
- Handle in accordance with good industrial hygiene and safety procedures.

Packaging material: Use approved materials suitable for corrosive liquids.

Shelf-life: 12 months in the original packaging.

6. **OTHER INFORMATION**

-

7. **THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	SOPURCLEAN CIP OP				
Authorisation number	EU-0021157-0008 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Octanoic acid		Active Substance	124-07-2	204-677-5	1,8
Decanoic acid		Active Substance	334-48-5	206-376-4	1,2
Sulfuric acid		Non-active substance	7664-93-9	231-639-5	4,68
Methane sulfonic acid		Non-active substance	75-75-2	200-898-6	20,3

COMMISSION IMPLEMENTING REGULATION (EU) 2020/581**of 27 April 2020****amending Implementing Regulation (EU) 2018/659 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC ⁽¹⁾, and in particular Article 17(3) thereof,

Having regard to Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae ⁽²⁾, and in particular Article 12(1) and (4), Article 13(2), Article 16 and Article 19(b) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/659 ⁽³⁾ lays down the conditions for entry into the Union of equidae and of semen, ova and embryos of equidae. It sets out the list of third countries from where Member States are to authorise the entry of equidae and of semen, ova and embryos of animals of the equine species, and specifies the animal health and veterinary certification conditions for such entries.
- (2) Directive 2009/156/EC lays down the animal health requirements governing imports of equidae into the Union. It provides that imports of equidae into the Union are only authorised from third countries or parts of the territory thereof which have been free from glanders (*Burholderia mallei*) for a period of at least six months.
- (3) On 25 December 2019, Turkey notified through the Animal Disease Notification System, that a case of glanders was confirmed on 4 December 2019 in a horse on the Büyükada Island, Province of Istanbul, Turkey. The entry into the Union of equidae and of germinal products of equidae from Turkey should be suspended for a period of at least 6 months. It is therefore necessary to amend the entry for Turkey in Annex I to Implementing Regulation (EU) 2018/659.
- (4) A new Show Jumping League has been established in the United Arab Emirates under the auspices of the Fédération Equestre Internationale ('FEI') which includes qualifying tests for the Show Jumping World Cup. Based on the animal health guarantees provided by the United Arab Emirates, adding the series of show jumping competitions of the United Arab Emirates International Show Jumping League to the list of events for which the re-entry into the Union after a temporary export of less than 90 days is authorised is justified. It is therefore necessary to amend the model health certificate and the model declaration set out in Chapter 1 of Section B of Part 2 of Annex II to Implementing Regulation (EU) 2018/659.
- (5) Implementing Regulation (EU) 2018/659 should therefore be amended accordingly.
- (6) In order to avoid a negative impact on trade, it is necessary to provide for a transitional period until 31 October 2020 during which animal health certificates issued in accordance with Implementing Regulation (EU) 2018/659, as amended by Implementing Regulation (EU) 2019/2147 ⁽⁴⁾, shall be accepted provided they are issued prior to 21 October 2020.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 14.9.1992, p. 54.

⁽²⁾ OJ L 192, 23.7.2010, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2018/659 of 12 April 2018 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae (OJ L 110, 30.4.2018, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/2147 of 28 November 2019 amending and correcting Implementing Regulation (EU) 2018/659 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae (OJ L 325, 16.12.2019, p. 99).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2018/659 is amended as follows:

- (1) In Annex I, the entry for Turkey is amended in accordance with Annex I to this Regulation.
- (2) In Annex II, Chapter 1 of Section B of Part 2 is replaced by the text set out in Annex II to this Regulation.

Article 2

Until 31 October 2020, Member States shall authorise the re-entry into the Union of registered horses accompanied by the relevant animal health certificate drawn up in accordance with the model health certificate set out in Chapter 1 of Section B of Part 2 of Annex II to Implementing Regulation (EU) 2018/659, as amended by Implementing Regulation (EU) 2019/2147, provided that the animal health certificate was issued prior to 21 October 2020.

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, 27 April 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX I

In Annex I to Implementing Regulation (EU) 2018/659, in the list of third countries and parts of the territory of third countries from which the entry into the Union of consignments of equidae and of semen, ova and embryos of equidae is authorised, the entry for Turkey is replaced by the following:

[illegible]

ANNEX II

In Section B of Part 2 of Annex II to Implementing Regulation (EU) 2018/659, Chapter 1 is replaced by the following:

‘Chapter 1

Model health certificate and model declaration applicable to re-entry into the Union of registered horses for competition after temporary export for a period of not more than 90 days to participate in equestrian events organised under the auspices of the Fédération Equestre Internationale (FEI)

(Test event in preparation of the Olympic Games, Olympic Games, Paralympics, World Equestrian Games/World Championship, Asian Equestrian Games, American Equestrian Games (including the PanAmerican Games, South American Games, Central American and Caribbean Games), Endurance World Cup in United Arab Emirates, LG Global Champions Tour, United Arab Emirates International Show Jumping League)

COUNTRY:

Veterinary certificate to EU

Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.				I.2. Certificate reference No		I.2.a.	
					I.3. Central competent authority			
					I.4. Local competent authority			
	I.5. Consignee Name Address Postcode Tel.				I.6.			
	I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
	I.11. Place of origin Name Address Approval number				I.12. Place of destination Name Address Postcode			
	I.13. Place of loading				I.14. Date of departure			
	I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification Documentary references				I.16. Entry BIP in EU			
					I.17. No(s) of CITES			
	I.18. Description of animal						I.19. Commodity code (HS code) 01 01	
							I.20. Quantity 1	
	I.21.						I.22. Number of packages	
	I.23. Seal/Container No						I.24.	
	I.25. Animal certified for: Registered horse ☐							
	I.26.				I.27. For import or admission into EU ☐			
I.28. Identification of the animal Species (Scientific name) Identification system Identification number Age Sex Equus caballus								

COUNTRY

Re-entry after temporary export of not more than 90 days
Specific competitions – Registered horse

	II.a. Certificate reference number	II.b. Local reference number
Part II: Certification	II. Attestation of animal health and welfare I, the undersigned official veterinarian, hereby certify, that the animal described in Box I.28.: — is a registered horse as defined in Article 2(c) of Commission Implementing Regulation (EU) 2018/659; — was examined today⁽¹⁾ and found free of clinical signs of diseases and of obvious signs of ectoparasite infestation; — is not intended for slaughter under a national programme of infectious or contagious disease eradication; — meets the requirements attested in points II.1. to II.3. of this certificate; — is accompanied by the written declaration, signed by the owner of the horse, or the representative of the owner.	
	II.1. <i>Attestation on third country or part of the territory of third country and holding of dispatch</i> II.1.1. The animal is dispatched from(insert name of country or part of the territory of a country), a country or part of the territory of a country which on the date of issuing this certificate has the Code:⁽²⁾ and is assigned to Sanitary Group⁽²⁾; II.1.2. in the country of dispatch the following diseases are compulsorily notifiable: African horse sickness, dourine (<i>Trypanosoma equiperdum</i>), glanders (<i>Burkholderia mallei</i>), equine encephalomyelitis (of all types including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rabies and anthrax; II.1.3. the animal is dispatched from a country or part of the territory of a country: a) which is considered free from African horse sickness in accordance with Directive 2009/156/EC and in which there has been no clinical, serological (in unvaccinated equidae) or epidemiological evidence of African horse sickness during the period of 2 years prior to the date of dispatch and in which there have been no vaccinations against the disease during the period of 12 months prior to the date of dispatch; b) in which Venezuelan equine encephalomyelitis has not occurred during the period of 2 years prior to the date of dispatch; c) in which dourine has not occurred during the period of 6 months prior to the date of dispatch; d) in which glanders has not occurred during the period of 6 months prior to the date of dispatch; II.1.4. the animal does not come from a holding, and to the best of my knowledge for the time periods referred to in points II.1.4.1. to II.1.4.7. was not in contact with animals from holdings, which were subject to prohibition orders for the reasons referred to in points II.1.4.1. to II.1.4.7. and which last for: ⁽³⁾[II.1.4.1. in the case of equidae suspected of having contracted dourine, ⁽⁴⁾either [6 months beginning on the date of the last actual or possible contact with an animal suspected of having contracted dourine or infected with <i>Trypanosoma equiperdum</i>]; ⁽⁴⁾and/or [in the case of a stallion, until the animal is castrated;] ⁽⁴⁾and/or [30 days following the date of completion of the cleansing and disinfection of the premises after all animals of susceptible species have been slaughtered;] ⁽³⁾[II.1.4.2. in the case of glanders, ⁽⁴⁾either [6 months beginning on the day on which the equidae suffering from the disease or subjected with positive results to a test for the detection of the causative pathogen <i>Burkholderia mallei</i> or antibodies to that pathogen, were killed and destroyed;] ⁽⁴⁾and/or [30 days following the date of completion of the cleansing and disinfection of the premises after all animals of susceptible species have been killed and destroyed;]	

COUNTRY

Re-entry after temporary export of not more than 90 days
Specific competitions – Registered horse

	II.a. Certificate reference number	II.b. Local reference number
II.1.4.3.	in the case of equine encephalomyelitis of any type, (4) <i>either</i> [6 months beginning on the day on which the equidae suffering from the disease have been slaughtered;] (4) <i>and/or</i> [6 months beginning on the day on which the equidae infected with the virus causing West Nile Fever, Eastern equine encephalomyelitis or Western equine encephalomyelitis have died, been removed from the holding or fully recovered;] (4) <i>and/or</i> [30 days following the date of completion of the cleansing and disinfection of the premises after all animals of susceptible species have been slaughtered;]	
II.1.4.4.	in the case of equine infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining equine animals on the holding have shown a negative reaction in an agar gel immunodiffusion test (AGID or Coggins test) carried out on blood samples collected on two occasions 3 months apart;	
II.1.4.5.	in the case of vesicular stomatitis, (4) <i>either</i> [6 months following the last case;] (4) <i>and/or</i> [30 days following the date of completion of the cleansing and disinfection of the premises after all animals of susceptible species have been slaughtered;]	
II.1.4.6.	in the case of rabies, 30 days following the last case and the date of completion of the cleansing and disinfection of the premises;	
II.1.4.7.	in the case of anthrax, 15 days following the last case and the date of completion of the cleansing and disinfection of the premises;	
II.1.5.	to the best of my knowledge, during the period of 15 days prior to the date of dispatch the animal has not been in contact with equidae infected or suspected of an infectious or contagious disease.	
II.2.	<i>Attestation of residence and pre-export isolation</i>	
II.2.1.	The animal was imported into the country or part of the territory of the country of dispatch on (<i>insert date</i>) (4) <i>either</i> [directly from the EU Member State (<i>insert name of EU Member State</i>);] (4) <i>or</i> [from a country or part of the territory of a country (<i>insert name of country</i>) under conditions at least as strict as those set out in this certificate;]	
II.2.2.	the animal exited from the Union (4) <i>either</i> [less than 30 days ago, and since exit from the Union was never in a country, or part of the territory of a country other than those of the same Sanitary Group. In the country or part of the territory of the country of dispatch it was resident on holdings under veterinary supervision, accommodated in separated stables without coming into contact with equidae of lower health status except during competition, and it has taken part in or was stabled together with horses participating in the LG Global Champions Tour (4) <i>either</i> [in the Metropolitan area of Mexico City, Mexico;] (4) <i>and/or</i> [in Miami, United States of America;] (4) <i>or</i> [in Shanghai, China;]]	

COUNTRY

Re-entry after temporary export of not more than 90 days
Specific competitions – Registered horse

	II.a. Certificate reference number	II.b. Local reference number
⁽⁴⁾or [less than 60 days ago, and since exit from the Union was never in a country, or part of the territory of a country other than those of the same Sanitary Group. In the country or part of the territory of the country of dispatch it was resident on holdings under veterinary supervision, accommodated in separated stables without coming into contact with equidae of lower health status except during competition and it has taken part in or was stabled together with horses participating in ⁽⁴⁾either [the Asian Games in(insert place).]] ⁽⁴⁾or [the American Games⁽⁵⁾ in(insert place).]] ⁽⁴⁾or [the Endurance World Cup in United Arab Emirates.]] ⁽⁴⁾or [less than 90 days ago, and since exit from the Union was never in a country, or part of the territory of a country⁽¹⁾ other than those of the same Sanitary Group. In the country or part of the territory of the country of dispatch it was resident on holdings under veterinary supervision, accommodated in separated stables without coming into contact with equidae of lower health status except during competition and it has taken part in or was stabled together with horses participating in ⁽⁴⁾either [the Test event for the Olympic Games in(insert place).]] ⁽⁴⁾or [the Olympic Games in(insert place).]] ⁽⁴⁾or [the Paralympics in(insert place).]] ⁽⁴⁾or [the World Equestrian Games/World Championships in(insert place).]] ⁽⁴⁾or [the United Arab Emirates International Show Jumping League.]]		
II.3. <i>Attestation of animal welfare</i>		
The animal described in Box I.28. was examined today⁽¹⁾ and found fit to be transported on the intended journey and arrangements were made to protect its health and well-being effectively at all stages of the journey.		
Notes: Part I: Box I.8.: Provide the code of the country or part of the territory of the country as appearing in column 3 of Annex I to Commission Implementing Regulation (EU) 2018/659. Box I.15.: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship) and information is to be provided. In case of unloading and reloading, the consignor must inform the Border Inspection Post of entry into the Union. Box I.23.: The container number and the seal number (if applicable) should be included. Box I.28.: <i>Identification system:</i> The animal must bear an individual identifier which permits to link the animal to the identification document as defined in Article 2(b) of Commission Implementing Regulation (EU) 2018/659. Specify the identification system (such as ear tag, tattoo, brand, transponder) and the anatomic place used on the animal. The number of the accompanying passport must be stated and the name of the competent authority which validated it. Age: Date of birth (dd/mm/yyyy). Sex (M = male, F = female, C = castrated).		

COUNTRY

Re-entry after temporary export of not more than 90 days
Specific competitions – Registered horse

	II.a. Certificate reference number	II.b. Local reference number
Part II: (1) The certificate must be issued on the day of loading or on the last working day before loading of the animal for dispatch to the Member State of destination in the Union. The re-entry after temporary export of this registered horse shall not be allowed when the animal was loaded either prior to the date of authorisation for re-entry into the Union from the respective country or the part of the territory of the country referred to in point II.1.1., or during a period where restrictive measures have been adopted by the Union against the entry of equidae from this country or this part of the territory of the country of dispatch. (2) Code of the country or part of the territory of the country, and the Sanitary Group as appearing in columns 3 and 5 respectively of Annex I to Commission Implementing Regulation (EU) 2018/659. (3) Delete statement if the attestation in point II.1.3. applies to the entire country of dispatch. (4) Delete as appropriate. (5) Including the PanAmerican Games, South American Games, Central American and Caribbean Games. This health certificate shall: (a) be drawn up in at least a language understood by the certifying officer and one of the official languages of the Member State of destination and of the Member State where the registered horse will enter Union territory and undergo the veterinary border checks; (b) be made out to a single consignee; (c) be signed and stamped in a colour different to the colour of the printing; (d) consist of a single sheet of paper or all sheets of paper required are part of an integrated whole and indivisible by inserting page numbers and total number of pages, and each page shall bear the certificate reference number at the top of the page and those pages are stapled and stamped.		
Official veterinarian Name (in capital letters): Date: Stamp: Qualification and title: Signature:		

Declaration by the owner or representative of the owner for the re-entry after temporary export of a registered horse for competition				
Identification of the animal ⁽¹⁾				
Species (Scientific name)	Identification system	Identification number	Age	Sex
<i>Equus caballus</i>				
I, the undersigned owner⁽²⁾ or representative of the owner⁽²⁾ of the registered horse described above, hereby declare, that: — the horse ^{(2)either} [was temporarily exported from the Union to the country of dispatch on..... (<i>insert date</i>) less than 60 days⁽²⁾ or 90 days⁽²⁾ prior to this declaration;] ^{(2)or} [entered the country of dispatch on (<i>insert date</i>) from.....(<i>insert name of country from where horse entered country of dispatch</i>);] — the horse has been temporarily exported from the Union to take part in ^{(2)either} [the Asian Games in(<i>insert place</i>);] ^{(2)or} [the American Games⁽³⁾ in(<i>insert place</i>);] ^{(2)or} [the Endurance World Cup in United Arab Emirates;] ^{(2)or} [the Test event for the Olympic Games in(<i>insert place</i>);] ^{(2)or} [the Olympic Games in(<i>insert place</i>);] ^{(2)or} [the Paralympics in(<i>insert place</i>);] ^{(2)or} [the World Equestrian Games/World Championships in(<i>insert place</i>);] ^{(2)or} [the LG Global Champions Tour in ^{(2)either} [the Metropolitan area of Mexico City, Mexico;] ^{(2)and/or} [Miami, United States of America;] ^{(2)or} [Shanghai, China;] ^{(2)or} [the United Arab Emirates International Show Jumping League.] — during the period of 15 days prior to the date of dispatch the horse has not been in contact with animals suffering from infectious or contagious diseases transmissible to equidae; — the conditions for residence and pre-export isolation as applicable in accordance with point II.2. of the accompanying health certificate for the country or part of the territory of the country of dispatch are fulfilled; — the transportation will be effected in such a way that health and well-being of the horse can be protected effectively at all stages of the journey. Name and address of the owner⁽²⁾ or representative⁽²⁾: Date:(<i>dd/mm/yyyy</i>) (<i>Signature</i>)				
⁽¹⁾ <i>Identification system</i>: The animal must bear an individual identifier which permits to link the animal to the identification document as defined in Article 2(b) of Commission Implementing Regulation (EU) 2018/659. Specify the identification system (such as ear tag, tattoo, brand, transponder) and the anatomic place used on the animal. If a passport accompanies the animal, its number should be stated and the name of the competent authority which validated it. <i>Age</i>: Date of birth (<i>dd/mm/yyyy</i>). <i>Sex</i> (M = male, F = female, C = castrated). ⁽²⁾ Delete as appropriate. ⁽³⁾ Including the PanAmerican Games, South American Games, Central American and Caribbean Games.'				

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

EN