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)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	SOPURA N.V.
	Address	Rue de Trazegnies 199, 6180 COUR- CELLES, 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 (%)		
Common name	TOPAC name	Function	CAS number	EC number	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 sub- stance	7664-38-2	231-633-2	0,0	30,0
Nitric acid		Non-active sub- stance	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 sub- stance	79-14-1	201-180-5	0,0	4,2
Lactic acid		Non-active sub- stance	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

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
	THE ST C I

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 na	H IDA C	Formation	CAS must be a	F.C	Content (%)	
	IUPAC name	Function	CAS number	EC number	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
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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 Pediococcus damnosus, 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

Use # 2 – Dipping/soaking

Table 2

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 % In case of outbreaks of Pediococcus damnosus, the produmust be used at 2 % v/v. Contact time: minimum 15 minu 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 pH ≤ 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

	1						
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 sub- stance	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 sub- stance	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
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s) PT04 – Food and feed area (Disinfectants)	Product type(s)	PT04 – Food and feed area (Disinfectants)
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2. META SPC 2 COMPOSITION

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

Common name IUPAC name		Function	CAS number	EC number	Content (%)	
Common name	TOPAC name	Function	CAS number	EC number	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
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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.
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

PT04 – Food and feed area (Disinfectants)			
-			
Bacteria Yeasts			
Indoor In food and feed areas			
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			
For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v In case of outbreaks of Pediococcus damnosus, 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.			
Industrial Trained professional			
 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. 			

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 Pediococcus damnosus, the product must be used at 1,5 %. Contact time: minimum 15 minutes at +4 °C and above, up to $+20-25 \text{ °C}$.			
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.			

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

PT04 – Food and feed area (Disinfectants)
-
Bacteria Yeast
Indoor In food and feed areas
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.
Maximum application rate: 100 mL/m² – For an effect on bacteria and on yeasts: Dilution rate: 1 %v/v. 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.
Industrial Trained professional
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.

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.

 $\textbf{4.3.4.} \ \ \textbf{Where specific to the use, the instructions for safe disposal of the product and its packaging}$

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 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. 		
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.		

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

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 solutionis 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 $^{\circ}$ C and above, up to +20– 25 $^{\circ}$ 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

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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 sub- stance	79-09-4	201-176-3	19,5
Phosphoric acid		Non-active sub- stance	7664-38-2	231-633-2	3,8
Lactic acid		Non-active sub- stance	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
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1.2. Suffix to the authorisation number

1.3. **Product type(s)**

Product type(s)	PT04 – Food and feed area (Disinfectants)
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2. META SPC 3 COMPOSITION

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

Common name IUPAC name Function		CAS number	FC	Content (%)		
Common name	TOPAC name	Function	CAS number	EC number	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 (%)	
	TOFAC Haine	runction	CAS number	EC number	Min	Max
Sulfuric acid		Non-active sub- stance	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 sub- stance	7664-38-2	231-633-2	0,0	0,0
Nitric acid		Non-active sub- stance	7697-37-2	231-714-2	18,0	18,0
Methane sulfonic acid		Non-active sub- stance	75-75-2	200-898-6	0,0	0,0
Glycolic acid		Non-active sub- stance	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

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

Table 7

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 Pediococcus damnosus, 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.

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 (3) 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.

⁽³⁾ 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**

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

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

Trade name(s)	SOPURCLEAN OP	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

1.2. Suffix to the authorisation number

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

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 sub- stance	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 sub- stance	7697-37-2	231-714-2	0,0	0,0
Methane sulfonic acid		Non-active sub- stance	75-75-2	200-898-6	20,3	20,3
Glycolic acid		Non-active sub- stance	79-14-1	201-180-5	0,0	0,0
Lactic acid		Non-active sub- stance	79-33-4	201-196-2	0,0	0,0
Citric acid		Non-active sub- stance	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

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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

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

Table 8

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 Pediococcus damnosus, 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).

^(*) 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**

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

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

Trade name(s)	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 sub- stance	7664-93-9	231-639-5	4,68
Methane sulfonic acid		Non-active sub- stance	75-75-2	200-898-6	20,3