

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

**schülke** 

## **thermosept® EndoCleaner**      **No Change Service!**

Version                      Revision Date:                      Date of last issue: 16.05.2022  
04.05                      09.04.2024

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### **SECTION 1: Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product identifier**

Trade name                      :    thermosept® EndoCleaner

#### **1.2 Relevant identified uses of the substance or mixture and uses advised against**

Use of the Sub-                      :    Cleaning agent  
stance/Mixture

Recommended restrictions        :    Restricted to professional users.  
on use

#### **1.3 Details of the supplier of the safety data sheet**

Producer                      :    Schülke & Mayr GmbH  
Robert-Koch-Str. 2  
  
22851 Norderstedt  
Germany  
Telephone: +49 (0)40/ 52100-0  
Telefax: +49 (0)40/ 52100318  
mail@schuelke.com  
www.schuelke.com

Supplier                      :    Schülke & Mayr UK Ltd.  
Cygnet House  
1, Jenkin Road  
  
Sheffield S9 1AT  
United Kingdom  
Telephone: +44 114 254 35 00  
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mail.uk@schulke.com

E-mail address of person        :    Application Specialists  
responsible for the                      +49 (0)40/ 521 00 666  
SDS/Contact person                      AD@schuelke.com

#### **1.4 Emergency telephone number**

Emergency telephone num-        :    Carechem 24 International:+44 1235 239670  
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### **SECTION 2: Hazards identification**

#### **2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Skin irritation, Category 2                      H315: Causes skin irritation.  
Eye irritation, Category 2                      H319: Causes serious eye irritation.

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### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms

:



Signal word

:

Warning

Hazard statements

:

H315 Causes skin irritation.  
H319 Causes serious eye irritation.

Precautionary statements

:

**Prevention:**

P280 Wear protective gloves/ eye protection/ face protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/ attention.

### **Additional Labelling**

EUH208 Contains subtilisin. May produce an allergic reaction.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

Chemical nature : Solution of the following substances with harmless additives.

#### **Hazardous components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
sodium p-cumenesulphonate	15763-76-5 239-854-6 - - - 01-2119489411-37-XXXX	Eye Irrit. 2; H319	>= 1 - < 10
2-aminoethanol	141-43-5 205-483-3	Acute Tox. 4; H302 Acute Tox. 4; H332	>= 2.5 - < 3

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	603-030-00-8 01-2119486455-28-XXXX	Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 (Respiratory system) Aquatic Chronic 3; H412  specific concentration limit STOT SE 3; H335 ≥ 5 %	
sodium etasulfate	126-92-1 204-812-8 --- 01-2119971586-23-XXXX	Skin Irrit. 2; H315 Eye Dam. 1; H318  specific concentration limit Eye Irrit. 2; H319 > 10 - < 20 % Eye Dam. 1; H318 > 20 %	≥ 1 - < 3
Alcohols, C12-15-branched and linear, ethoxylated propoxylated	120313-48-6 --- --- ---	Skin Irrit. 2; H315 Aquatic Acute 1; H400 Aquatic Chronic 3; H412  M-Factor (Acute aquatic toxicity): 1	≥ 0.25 - < 1
Alcohols, C13-15-branched and linear, butoxylated ethoxylated	111905-53-4 --- --- ---	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 3; H412  M-Factor (Acute aquatic toxicity): 1	≥ 0.25 - < 1
subtilisin	9014-01-1 232-752-2 647-012-00-8 01-2119480434-38-XXXX	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1; H334 STOT SE 3; H335 (Respiratory system) Aquatic Acute 1; H400 Aquatic Chronic 2; H411	≥ 0.1 - < 0.25

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		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Substances with a workplace exposure limit :			
propane-1,2-diol	57-55-6 200-338-0 - - - 01-2119456809-23-XXXX		>= 10 - < 20
glycerol	56-81-5 200-289-5 - - - - - -		>= 10 - < 20

For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

### **4.1 Description of first aid measures**

- General advice : Take off all contaminated clothing immediately.
- If inhaled : If symptoms persist, call a physician.
- In case of skin contact : Wash off immediately with soap and plenty of water.  
If skin irritation persists, call a physician.
- In case of eye contact : Rinse thoroughly with plenty of water, also under the eyelids.  
If eye irritation persists, consult a specialist.
- If swallowed : Do NOT induce vomiting.  
Drink water as a precaution.  
Call a physician immediately.

### **4.2 Most important symptoms and effects, both acute and delayed**

- Symptoms : Treat symptomatically.
- Risks : Causes skin irritation.  
Causes serious eye irritation.

### **4.3 Indication of any immediate medical attention and special treatment needed**

- Treatment : For specialist advice physicians should contact the Poisons Information Service.

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### **SECTION 5: Firefighting measures**

#### **5.1 Extinguishing media**

Suitable extinguishing media : Dry powder  
Carbon dioxide (CO<sub>2</sub>)  
Foam  
Water spray jet

Unsuitable extinguishing media : Do NOT use water jet.

#### **5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : Carbon dioxide (CO<sub>2</sub>)  
Carbon monoxide  
Nitrogen oxides (NO<sub>x</sub>)

#### **5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

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### **SECTION 6: Accidental release measures**

#### **6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Increased risk of slipping in the presence of leaked / spilled product.

#### **6.2 Environmental precautions**

Environmental precautions : Avoid subsoil penetration.

#### **6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).  
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

#### **6.4 Reference to other sections**

see Section 8 + 13

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### **SECTION 7: Handling and storage**

#### **7.1 Precautions for safe handling**

Advice on safe handling : Wear personal protective equipment.  
Never mix concentrates directly.

Advice on protection against fire and explosion : Normal measures for preventive fire protection. The product itself does not burn.

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Hygiene measures                      :    Keep away from food and drink.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage                      :    Store at room temperature in the original container.  
areas and containers

Further information on stor-                      :    Recommended storage temperature: 5 - 25°C Protect from  
age conditions                      frost, heat and direct sunlight.

Advice on common storage                      :    Do not store together with explosive, infectious and radioactive  
products.

### 7.3 Specific end use(s)

Specific use(s)                      :    none

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
propane-1,2-diol	57-55-6	TWA (particles)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Total vapour and particles)	150 ppm 474 mg/m <sup>3</sup>	GB EH40
glycerol	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	GB EH40
2-aminoethanol	141-43-5	TWA	1 ppm 2.5 mg/m <sup>3</sup>	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		STEL	3 ppm 7.6 mg/m <sup>3</sup>	GB EH40
	Further information: Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity.			
		TWA	1 ppm 2.5 mg/m <sup>3</sup>	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
		STEL	3 ppm 7.6 mg/m <sup>3</sup>	2006/15/EC
	Further information: Indicative, Identifies the possibility of significant uptake through the skin			
subtilisin	9014-01-1	TWA	0.00004 mg/m <sup>3</sup>	GB EH40
	Further information: Capable of causing occupational asthma.			

#### Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
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propane-1,2-diol	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Workers	Inhalation	Long-term local effects	10 mg/m3
sodium p-cumenesulphonate	Workers	Skin contact	Long-term systemic effects	191 mg/kg
	Workers	Skin contact	Long-term local effects	0.096 mg/cm2
	Workers	Inhalation	Long-term systemic effects	37.4 mg/m3
Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3)	Workers	Inhalation	Acute local effects, Acute systemic effects	40 mg/m3
	Workers	Inhalation	Long-term local effects	4 mg/m3
	Workers	Inhalation	Long-term systemic effects	40 mg/m3
2-aminoethanol	Workers	Skin contact	Long-term systemic effects	1 mg/kg
	Workers	Inhalation	Long-term local effects	3.3 mg/m3
sodium etasulfate	Workers	Skin contact	Long-term systemic effects	4060 mg/kg
	Workers	Inhalation	Long-term systemic effects	285 mg/m3
subtilisin	Workers	Skin contact	Acute local effects, Long-term local effects	2000 ppm
	Workers	Inhalation	Long-term local effects	0.00006 mg/m3

### Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
propane-1,2-diol	Fresh water	260 mg/l
	Marine water	26 mg/l
	Intermittent use/release	183 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg
	Marine sediment	57.2 mg/kg
sodium p-cumenesulphonate	Fresh water	0.1 mg/l
	Marine water	0.01 mg/l
	Intermittent use/release	1 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.372 mg/kg
	Marine sediment	0.0372 mg/kg
Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3)	Fresh water	2 mg/l
	Marine water	0.2 mg/l
	Intermittent use/release	1 mg/l
	Fresh water sediment	24 mg/kg
	Sewage treatment plant	100 mg/l

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	Soil	2.5 mg/kg
2-aminoethanol	Fresh water	0.085 mg/l
	Marine water	0.0085 mg/l
	Intermittent use/release	0.028 mg/l
	Effects on waste water treatment plants	100 mg/l
	Fresh water sediment	0.434 mg/kg dry weight (d.w.)
	Marine sediment	0.0434 mg/kg dry weight (d.w.)
	Soil	0.0367 mg/kg dry weight (d.w.)
sodium etasulfate	Fresh water	0.136 mg/l
	Marine water	0.0136 mg/l
	Fresh water sediment	1.5 mg/kg
	Marine sediment	0.15 mg/kg
	Soil	0.22 mg/kg
	Effects on waste water treatment plants	1.35 mg/l
subtilisin	Fresh water	0.00006 mg/l
	Marine water	0.000006 mg/l
	Effects on waste water treatment plants	65 mg/l

## 8.2 Exposure controls

### Personal protective equipment

- Eye/face protection : Safety glasses with side-shields conforming to EN166
- Hand protection  
Directive : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.
- Remarks : Splash protection: disposable nitrile rubber gloves e.g. Dermatril (layer thickness: 0.11 mm) made by KCL or gloves from other manufacturers offering the same protection. Prolonged contact: Nitrile rubber gloves e.g. Camatril (>480 Min., layer thickness: 0,40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0,70 mm) made by KCL or gloves from other manufacturers offering the same protection.
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : No personal respiratory protective equipment normally required.
- Protective measures : Avoid contact with skin and eyes.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : liquid
- Colour : light yellow
- Odour : characteristic
- Odour Threshold : not determined
- pH : 11 (20 °C)  
Concentration: 100 %



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Melting point/freezing point	:	< -5 °C
Decomposition temperature	:	Not applicable
Initial boiling point and boiling range	:	ca. 100 °C
Flash point	:	> 100 °C Method: DIN 51755 Part 1
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	ca. 1.11 g/cm <sup>3</sup> (20 °C, 1,013 hPa)
Solubility(ies)	:	
Water solubility	:	completely soluble (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	ca. 9 mPa*s Method: ISO 3219
Viscosity, kinematic	:	not determined
Explosive properties	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### **9.2 Other information**

Flammability (liquids)	:	Does not sustain combustion.
Metal corrosion rate	:	None reasonably foreseeable.

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## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

No dangerous reaction known under conditions of normal use.

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### 10.2 Chemical stability

The product is chemically stable.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

### 10.4 Conditions to avoid

Conditions to avoid : Protect from frost, heat and sunlight.

### 10.5 Incompatible materials

Materials to avoid : Possible incompatibility with alkali sensitive materials.

### 10.6 Hazardous decomposition products

None reasonably foreseeable.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg  
Method: Calculation method

#### **Components:**

##### **sodium p-cumenesulphonate:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

##### **2-aminoethanol:**

Acute oral toxicity : (Rat): 1,515 mg/kg  
Method: OECD Test Guideline 401  
Assessment: Harmful if swallowed.

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Acute inhalation toxicity : (Rat): > 1.3 mg/l  
Exposure time: 6 h  
Test atmosphere: vapour  
Assessment: Harmful if inhaled.

Acute dermal toxicity : Assessment: Harmful in contact with skin.

### **sodium etasulfate:**

Acute oral toxicity : LD50 (Rat): 2,840 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: Calculated value

Acute inhalation toxicity : Remarks: not determined

Acute dermal toxicity : Remarks: not determined

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

### **subtilisin:**

Acute oral toxicity : LD50 (Rat): 1,800 mg/kg  
Method: OECD Test Guideline 401

Acute dermal toxicity : Remarks: No data available

### **propane-1,2-diol:**

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg

Acute inhalation toxicity : LC50 (Rabbit): 317.042 mg/l  
Exposure time: 2 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

### **glycerol:**

Acute oral toxicity : LD50 (Rat, female): 27,200 mg/kg  
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): > 5.85 mg/l  
Exposure time: 4 h

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Test atmosphere: dust/mist  
Method: OECD Test Guideline 412  
Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg

### **Skin corrosion/irritation**

Causes skin irritation.

### **Components:**

#### **sodium p-cumenesulphonate:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : slight irritation  
Remarks : Based on available data, the classification criteria are not met.

#### **2-aminoethanol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Corrosive after 3 minutes to 1 hour of exposure

#### **sodium etasulfate:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Skin irritation

#### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Species : Rabbit  
Method : Draize Test  
Result : Skin irritation

#### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Mild skin irritation

#### **subtilisin:**

Method : OECD Test Guideline 404  
Result : Skin irritation

#### **propane-1,2-diol:**

Result : No skin irritation

### **Serious eye damage/eye irritation**

Causes serious eye irritation.

### **Components:**

#### **sodium p-cumenesulphonate:**

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Species                      : Rabbit  
Method                      : OECD Test Guideline 405  
Result                        : Eye irritation

### **2-aminoethanol:**

Species                      : Rabbit  
Method                      : OECD Test Guideline 405  
Result                        : Risk of serious damage to eyes.

### **sodium etasulfate:**

Species                      : Rabbit  
Method                      : OECD Test Guideline 405  
Result                        : Irreversible effects on the eye

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Species                      : Rabbit  
Method                      : OECD Test Guideline 405  
Result                        : No eye irritation

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Species                      : Rabbit  
Method                      : OECD Test Guideline 405  
Result                        : Eye irritation

### **subtilisin:**

Method                      : OECD Test Guideline 405  
Result                        : Irreversible effects on the eye

### **propane-1,2-diol:**

Result                        : Mildly irritant - does not need to be labelled

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

Test Type                    : Buehler Test  
Species                      : Guinea pig  
Method                      : OECD Test Guideline 406  
Result                        : Did not cause sensitisation on laboratory animals.

#### **2-aminoethanol:**

Test Type                    : Maximisation Test

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Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : Did not cause sensitisation on laboratory animals.

### **sodium etasulfate:**

Method : OECD Test Guideline 429  
Result : Did not cause sensitisation on laboratory animals.

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Remarks : No data available

### **subtilisin:**

Result : Probability of respiratory sensitisation in humans based on animal testing  
Remarks : largely based on human evidence

### **propane-1,2-diol:**

Result : Does not cause skin sensitisation.

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

Genotoxicity in vitro : Test Type: Mutagenicity (Salmonella typhimurium - reverse mutation assay)  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: Not mutagenic in Ames Test

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

#### **2-aminoethanol:**

Genotoxicity in vitro : Result: Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Genotoxicity in vivo : Result: Did not show mutagenic effects in animal experiments.

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects., Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

#### **sodium etasulfate:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)

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Test system: Bacteria  
Method: OECD Test Guideline 471  
Result: negative

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Result: negative

Germ cell mutagenicity- Assessment : Based on available data, the classification criteria are not met.

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Result: negative

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

### **subtilisin:**

Genotoxicity in vitro : Method: OECD Test Guideline 471  
Result: Non mutagenic

Germ cell mutagenicity- Assessment : Animal testing did not show any mutagenic effects.

### **propane-1,2-diol:**

Germ cell mutagenicity- Assessment : Non mutagenic

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

Species : Rat  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : no increase in tumors observed

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

#### **2-aminoethanol:**

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

#### **sodium etasulfate:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Dose : > 1125 mg/kg body weight

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Carcinogenicity - Assessment : Weight of evidence does not support classification as a car-

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|| ment cinogen

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

|| Carcinogenicity - Assessment : No data available

### **subtilisin:**

|| Carcinogenicity - Assessment : No data available

### **propane-1,2-diol:**

|| Result : negative

|| Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

|| Effects on fertility : Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 300 mg/kg bw/day  
General Toxicity F1: NOAEL: 1,000 mg/kg bw/day  
Method: OECD Test Guideline 421

|| Effects on foetal development : Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 936 mg/kg body weight  
Teratogenicity: NOAEL: 936 mg/kg bw/day

|| Reproductive toxicity - Assessment : study scientifically unjustified

#### **2-aminoethanol:**

|| Effects on fertility : Test Type: Two-generation study  
Species: Rat  
Application Route: Oral  
General Toxicity - Parent: NOAEL: 300 mg/kg body weight  
General Toxicity F1: NOAEL: 1,000 mg/kg body weight  
General Toxicity F2: NOAEL: 1,000 mg/kg body weight  
Method: OECD Test Guideline 416  
Result: Animal testing did not show any effects on fertility.

|| Effects on foetal development : Species: Rat  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 120 mg/kg bw/day  
Teratogenicity: NOAEL: 450 mg/kg bw/day  
Method: OECD Test Guideline 414  
Remarks: Based on available data, the classification criteria are not met.

|| Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.



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### Assessment

#### **sodium etasulfate:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 250 milligram per kilogram  
Result: negative  
Remarks: Did not show teratogenic effects in animal experiments.

Reproductive toxicity - Assessment : No data available

#### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Reproductive toxicity - Assessment : Based on available data, the classification criteria are not met.

#### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Reproductive toxicity - Assessment : No data available

#### **subtilisin:**

Reproductive toxicity - Assessment : No data available

#### **propane-1,2-diol:**

Reproductive toxicity - Assessment : Did not show carcinogenic or teratogenic effects in animal experiments.

### **STOT - single exposure**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

#### **2-aminoethanol:**

Assessment : May cause respiratory irritation.

#### **sodium etasulfate:**

Remarks : No data available

#### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Remarks : No data available

#### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Remarks : No data available

#### **subtilisin:**

Target Organs : Respiratory Tract

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|| Assessment : May cause respiratory irritation.

### **propane-1,2-diol:**

|| Assessment : Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Components:**

#### **sodium p-cumenesulphonate:**

|| Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

#### **2-aminoethanol:**

|| Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

#### **sodium etasulfate:**

|| Remarks : No data available

#### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

|| Remarks : No data available

#### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

|| Remarks : Not classified due to data which are conclusive although insufficient for classification.

### **Repeated dose toxicity**

### **Components:**

#### **sodium p-cumenesulphonate:**

|| Species : Rat  
|| NOAEL : 763 mg/kg  
|| Application Route : Oral  
|| Target Organs : Cardio-vascular system  
|| Remarks : Subchronic toxicity

|| Species : Rat  
|| NOAEL : 60 mg/kg  
|| Application Route : Dermal  
|| Exposure time : 2 yr  
|| Method : OECD Test Guideline 453  
|| Target Organs : Skin

#### **sodium etasulfate:**

|| Species : Rabbit  
|| NOAEL : 488 mg/kg

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Application Route : Oral  
Exposure time : 90-day

Species : Mouse  
NOAEL : 400 mg/kg  
Application Route : Skin contact  
Exposure time : 90-day

### **Aspiration toxicity**

Not classified based on available information.

### **Components:**

#### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Due to the viscosity, this product does not present an aspiration hazard.

#### **propane-1,2-diol:**

No aspiration toxicity classification

### **Experience with human exposure**

#### **Components:**

#### **2-aminoethanol:**

General Information : Repeated and prolonged exposure to solvents may cause brain and nervous system damage.

### **Further information**

#### **Product:**

Remarks : The product has not been tested.

---

## **SECTION 12: Ecological information**

### **12.1 Toxicity**

#### **Components:**

#### **sodium p-cumenesulphonate:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h

#### **2-aminoethanol:**

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): 349 mg/l  
Exposure time: 96 h  
Test Type: semi-static test

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	Method: Tested according to Directive 92/69/EEC.
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna): 65 mg/l Exposure time: 48 h Method: EG 84/449
Toxicity to algae/aquatic plants	: EC50 (Scenedesmus capricornutum (fresh water algae)): 2.5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: 1.2 mg/l Exposure time: 30 d Species: Oryzias latipes (Orange-red killifish)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0.85 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

### **sodium etasulfate:**

Toxicity to fish	: LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 483 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Desmodesmus subspicatus (green algae)): > 511 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	: NOEC: >= 1,357 mg/l Exposure time: 42 d Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 1.4 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Toxicity to fish	: LC50 (Leuciscus idus): 1 - 10 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna): 0.1 - 1 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (algae): 0.1 - 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.1 - < 1 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Toxicity to fish : LC50 (Leuciscus idus): > 1 - 10 mg/l  
Exposure time: 96 h  
Test Type: static test

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0.1 - < 1.0 mg/l  
Exposure time: 48 h  
Test Type: semi-static test  
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.1 - 1 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 202

### **subtilisin:**

Toxicity to fish : LC50 (Fish): 8.2 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna): 0.586 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (algae): 0.83 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC: 0.017 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity) : 1

### **propane-1,2-diol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss): 40,613 mg/l  
Exposure time: 96 h

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		Test Type: static test Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	LC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 19,000 mg/l Exposure time: 96 h Test Type: Growth inhibition Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 13,020 mg/l Exposure time: 7 d Species: Ceriodaphnia dubia (water flea)

### **glycerol:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 10,000 mg/l Exposure time: 24 h

## **12.2 Persistence and degradability**

### **Product:**

Biodegradability	:	Result: Readily biodegradable, according to appropriate OECD test. Method: OECD 301D / EEC 84/449 C6
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### **Components:**

#### **sodium p-cumenesulphonate:**

Biodegradability	:	Test Type: aerobic Result: Readily biodegradable. Biodegradation: > 60 % Exposure time: 28 d Method: OECD Test Guideline 301B
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#### **2-aminoethanol:**

Biodegradability	:	Test Type: aerobic Inoculum: activated sludge Result: Readily biodegradable. Biodegradation: > 90 % Exposure time: 21 d Method: OECD Test Guideline 301A
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### **sodium etasulfate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 89 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 60 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### **Alcohols, C13-15-branched and linear, butoxylated ethoxylated:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 90 - 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301A

### **subtilisin:**

Biodegradability : Result: Readily biodegradable.  
Method: OECD Test Guideline 301B

### **propane-1,2-diol:**

Biodegradability : Result: Readily biodegradable, according to appropriate  
OECD test.  
Biodegradation: 81 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

Result: Readily biodegradable, according to appropriate  
OECD test.  
Biodegradation: 96 %  
Exposure time: 64 d  
Method: OECD Test Guideline 306

## **12.3 Bioaccumulative potential**

### **Components:**

#### **sodium p-cumenesulphonate:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

#### **2-aminoethanol:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.91

#### **sodium etasulfate:**

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Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.248

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Bioaccumulation : Remarks: Accumulation in aquatic organisms is unlikely.

### **subtilisin:**

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: < 0

### **propane-1,2-diol:**

Bioaccumulation : Bioconcentration factor (BCF): 0.09  
Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: -1.07

### **glycerol:**

Partition coefficient: n-octanol/water : log Pow: -1.75 (25 °C)  
Method: OECD Test Guideline 107

## **12.4 Mobility in soil**

### **Components:**

#### **sodium p-cumenesulphonate:**

Mobility : Remarks: Not expected to adsorb on soil.

#### **2-aminoethanol:**

Mobility : Remarks: Not expected to adsorb on soil.

#### **sodium etasulfate:**

Mobility : Remarks: No data available

### **Alcohols, C12-15-branched and linear, ethoxylated propoxylated:**

Mobility : Remarks: Substance does not evaporate from water surface into the atmosphere., Adsorption to solid soil phase is possible.

### **subtilisin:**

Mobility : Remarks: No data available

### **propane-1,2-diol:**

Mobility : Medium: Soil  
Remarks: Mobile in soils



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Distribution among environmental compartments : Koc: < 1

### 12.5 Results of PBT and vPvB assessment

#### **Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

#### **Components:**

##### **propane-1,2-diol:**

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT).. This substance is not considered to be very persistent and very bioaccumulating (vPvB).

### 12.6 Other adverse effects

#### **Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Additional ecological information : No data is available on the product itself.

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Disposal together with normal waste is not allowed. Special disposal required according to local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

---

## SECTION 14: Transport information

### 14.1 UN number

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

### 14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

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**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### **14.3 Transport hazard class(es)**

**ADR** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA** : Not regulated as a dangerous good

### **14.4 Packing group**

**ADR** : Not regulated as a dangerous good

**IMDG** : Not regulated as a dangerous good

**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : Not regulated as a dangerous good

### **14.5 Environmental hazards**

Not regulated as a dangerous good

### **14.6 Special precautions for user**

Not applicable

### **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable for product as supplied.

---

## **SECTION 15: Regulatory information**

### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Volatile organic compounds (VOC) content: 3.71 %

according to Detergents Regulation EC 648/2004 : 5 - < 15%: Anionic surfactants  
< 5%: Non-ionic surfactants, Polycarboxylates  
Other constituents: Enzymes

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### **Other regulations:**

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### **The components of this product are reported in the following inventories:**

TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.  sodium p-cumenesulphonate Sodium polyacrylate
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
TECI	:	Not in compliance with the inventory

### **15.2 Chemical safety assessment**

**||** No Chemical Safety Assessment has been carried out for this mixture.

## **SECTION 16: Other information**

### **Full text of H-Statements**

H302	:	Harmful if swallowed.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H318	:	Causes serious eye damage.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	:	May cause respiratory irritation.
H400	:	Very toxic to aquatic life.
H411	:	Toxic to aquatic life with long lasting effects.

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H412 : Harmful to aquatic life with long lasting effects.

### **Full text of other abbreviations**

Acute Tox. : Acute toxicity  
Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Eye Dam. : Serious eye damage  
Eye Irrit. : Eye irritation  
Resp. Sens. : Respiratory sensitisation  
Skin Corr. : Skin corrosion  
Skin Irrit. : Skin irritation  
STOT SE : Specific target organ toxicity - single exposure  
2006/15/EC : Europe. Indicative occupational exposure limit values  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
2006/15/EC / TWA : Limit Value - eight hours  
2006/15/EC / STEL : Short term exposure limit  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

**Classification of the mixture:**

**Classification procedure:**

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **thermosept® EndoCleaner**

**No Change Service!**

Version  
04.05

Revision Date:  
09.04.2024

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Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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