

SAFETY DATA SHEET

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



thermosept® X-tra enzymatic cleaner **No Change Service!**

Version Revision Date: Date of last issue: 26.10.2023
05.04 09.04.2024

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

1.1 Product identifier

Trade name : thermosept® X-tra enzymatic cleaner
Unique Formula Identifier : 77M1-80KT-W00C-T8QU
(UFI)

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
Telefax: +44 114 254 35 01
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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SAFETY DATA SHEET

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



thermosept® X-tra enzymatic cleaner **No Change Service!**

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

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)

Not a hazardous substance or mixture.

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)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

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 etasulfate	126-92-1 204-812-8 - - - 01-2119971586-23-XXXX	Skin Irrit. 2; H315 Eye Dam. 1; H318 <hr/> specific concentration limit Eye Irrit. 2; H319 > 10 - < 20 % Eye Dam. 1; H318 > 20 %	>= 1 - < 3
Substances with a workplace exposure limit :			
propane-1,2-diol	57-55-6 200-338-0 - - - 01-2119456809-23-XXXX		>= 1 - < 10
glycerol	56-81-5 200-289-5 - - - - - -		>= 1 - < 10

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

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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 with water and soap as a precaution.
- In case of eye contact : Flush eyes with water as a precaution.
- If swallowed : Do NOT induce vomiting.
Drink water as a precaution.
If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

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

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Dry powder
Carbon dioxide (CO₂)
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 : No hazardous combustion products are known

5.3 Advice for firefighters

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

SAFETY DATA SHEET

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



thermosept® X-tra enzymatic cleaner **No Change Service!**

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Wear personal protective equipment.
Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : Avoid contact with skin, eyes and clothing.

7.2 Conditions for safe storage, including any incompatibilities

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

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

Advice on common storage : No special restrictions on storage with other 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 ³	GB EH40
		TWA (Total vapour and parti-	150 ppm 474 mg/m ³	GB EH40

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

		cles)		
glycerol	56-81-5	TWA (Mist)	10 mg/m ³	GB EH40

Derived No Effect Level (DNEL):

Substance name	End Use	Exposure routes	Potential health effects	Value
sodium etasulfate	Workers	Skin contact	Long-term systemic effects	4060 mg/kg
	Workers	Inhalation	Long-term systemic effects	285 mg/m ³
propane-1,2-diol	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Workers	Inhalation	Long-term local effects	10 mg/m ³
Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3)	Workers	Inhalation	Acute local effects, Acute systemic effects	40 mg/m ³
	Workers	Inhalation	Long-term local effects	4 mg/m ³
	Workers	Inhalation	Long-term systemic effects	40 mg/m ³
sodium etasulfate	Workers	Skin contact	Long-term systemic effects	4060 mg/kg
	Workers	Inhalation	Long-term systemic effects	285 mg/m ³

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
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
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
Alanine, N,N-bis(carboxymethyl)-, sodium salt (1:3)	Soil	50 mg/kg
	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
sodium etasulfate	Soil	2.5 mg/kg
	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

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

	Effects on waste water treatment plants	1.35 mg/l
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8.2 Exposure controls

Personal protective equipment

- Eye/face protection : No special protective equipment required.
Hand protection
Directive : No special protective equipment required.
Skin and body protection : No special protective equipment required.
Respiratory protection : No personal respiratory protective equipment normally required.
Protective measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : liquid
Colour : yellow
Odour : characteristic
Odour Threshold : not determined
pH : ca. 10.7 (20 °C)
Concentration: 100 %
Melting point/freezing point : < -5 °C
Decomposition temperature : Not applicable
Initial boiling point and boiling range : 102 °C
Flash point : > 102 °C
Method: ISO 3679
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. 1.06 g/cm³ (20 °C, 1,013 hPa)
Solubility(ies)
Water solubility : completely soluble (20 °C)
Partition coefficient: n- : Not applicable

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

octanol/water
Auto-ignition temperature : No data available

Viscosity
Viscosity, dynamic : ca. 4 mPa*s
Method: ISO 3219

Viscosity, kinematic : not determined

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : Does not sustain combustion.

Metal corrosion rate : < 6.25 mm/a
Not corrosive to metals Aluminium and Mild steel

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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.

Components:

sodium etasulfate:

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

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

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
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

Not classified based on available information.

Components:

sodium etasulfate:

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

propane-1,2-diol:

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

sodium etasulfate:

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

propane-1,2-diol:

Result : Mildly irritant - does not need to be labelled

SAFETY DATA SHEET

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

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thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

sodium etasulfate:

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

propane-1,2-diol:

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:

sodium etasulfate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Bacteria
Method: OECD Test Guideline 471
Result: negative

propane-1,2-diol:

Germ cell mutagenicity- Assessment : Non mutagenic

Carcinogenicity

Not classified based on available information.

Components:

sodium etasulfate:

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

propane-1,2-diol:

Result : negative

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

Reproductive toxicity

Not classified based on available information.

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

Components:

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

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 etasulfate:

Remarks : No data available

propane-1,2-diol:

Assessment : Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Components:

sodium etasulfate:

Remarks : No data available

Repeated dose toxicity

Components:

sodium etasulfate:

Species : Rabbit
NOAEL : 488 mg/kg
Application Route : Oral
Exposure time : 90-day

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

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

Aspiration toxicity

Not classified based on available information.

Components:

propane-1,2-diol:

No aspiration toxicity classification

Further information

Product:

Remarks : The product has not been tested.

SECTION 12: Ecological information

12.1 Toxicity

Components:

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)

propane-1,2-diol:

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

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 20,000 mg/l
Exposure time: 18 h

Toxicity to daphnia and other : NOEC: 13,020 mg/l
aquatic invertebrates (Chronic toxicity) : 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 : EC50 (*Daphnia magna* (Water flea)): > 10,000 mg/l
aquatic invertebrates : Exposure time: 24 h

12.2 Persistence and degradability

Product:

Biodegradability : Remarks: The biodegradability of the product has not been tested.

Components:

sodium etasulfate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 89 %
Exposure time: 28 d
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 etasulfate:

Bioaccumulation : Remarks: No data available

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

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

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 etasulfate:

Mobility : Remarks: No data available

propane-1,2-diol:

Mobility : Medium: Soil
Remarks: Mobile in soils

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.

SAFETY DATA SHEET

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



thermosept® X-tra enzymatic cleaner **No Change Service!**

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

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
- 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

SAFETY DATA SHEET

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

schülke 

thermosept® X-tra enzymatic cleaner *No Change Service!*

Version: 05.04 Revision Date: 09.04.2024 Date of last issue: 26.10.2023

- 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: 1.21 %
- according to Detergents Regulation EC 648/2004 : < 5%: Anionic surfactants, Non-ionic surfactants, Polycarboxylates
Other constituents: Enzymes

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

- AIIC : 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

- H315 : Causes skin irritation.
- H318 : Causes serious eye damage.

Full text of other abbreviations

- Eye Dam. : Serious eye damage
- Skin Irrit. : Skin irritation
- GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
- GB EH40 / TWA : Long-term exposure limit (8-hour TWA 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 La-

SAFETY DATA SHEET

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schülke 

thermosept® X-tra enzymatic cleaner **No Change Service!**

Version
05.04

Revision Date:
09.04.2024

Date of last issue: 26.10.2023

boratory 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

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.