

## thermosept® X.tra No Change Service!

Version	Revision Date:	Date of last issue: 28.02.2020
04.04	19.10.2020	Date of first issue: 03.04.2012

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

1.1 Product identifier	
Trade name :	thermosept® X-tra
1.2 Relevant identified uses of the s	ubstance or mixture and uses advised against
Use of the Sub- : stance/Mixture	Cleaning agent
Recommended restrictions : on use	Restricted to professional users.
1.3 Details of the supplier of the saf	ety data sheet
Manufacturer/ Supplier :	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, Meadowhall
	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 : responsible for the SDS/Contact person	Application Department +49 (0)40/ 521 00 666 AD@schuelke.com (Schülke & Mayr UK Ltd.: +44-1142543500)

#### 1.4 Emergency telephone number

Emergency telephone num-	: UK Poisons Emergency number: 0870 600 626	6
ber	Carechem 24 International:+44 1235 239670	

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

Classification (REGULATION	(EC) No 1272/2008)
Skin irritation, Category 2	H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation.

according to Regulation (EC) No. 1907/2006



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#### 2.2 Label elements

Labelling (REGULATION (E Hazard pictograms	EC)   :	No 1272/2008)
Signal word	:	Warning
Hazard Statements	:	<ul><li>H315 Causes skin irritation.</li><li>H319 Causes serious eye irritation.</li></ul>
Precautionary Statements	:	Prevention:P280Wear protective gloves/ eye protection/ face protection.Response:P302 + P352IF ON SKIN: Wash with plenty of soap and water.P305 + P351 + P338IF IN EYES: Rinse cautiously with wa- ter for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.P337 + P313If 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 additive
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#### 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	141-43-5 205-483-3 603-030-00-8	Acute Tox. 4; H302 Acute Tox. 4; H332 Acute Tox. 4; H312	>= 2.5 - < 3



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		01-2119486455-28- XXXX	Skin Corr. 1B; H314 Eye Dam. 1; H318 STOT SE 3; H335 Aquatic Chronic 3; H412	
sodium e	etasulfate	126-92-1 204-812-8  01-2119971586-23- XXXX	Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 1 - < 3
Alcohols, linear, etl	, C12-15-branched and hoxylated propoxylated	120313-48-6   	Skin Irrit. 2; H315 Aquatic Acute 1; H400; M = 1 Aquatic Chronic 3; H412	>= 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 Aquatic Acute 1; H400; M = 1 Aquatic Chronic 2; H411	>= 0.1 - < 0.25

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.		
4.3	4.3 Indication of any immediate medical attention and special treatment needed				
	Treatment	:	For specialist advice physicians should contact the Poisons		

Information Service.

according to Regulation (EC) No. 1907/2006



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#### **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 prod- ucts	:	Carbon dioxide (CO2) Carbon monoxide Nitrogen oxides (NOx)

#### 5.3 Advice for firefighters

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

#### **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 pro	otection against : osion	:	Normal measures for preventive fire protection. The product itself does not burn.
Advice on sa	fe handling	:	Wear personal protective equipment. Never mix concentrates directly.

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Hygiene measures	:	Keep away from food and drink.					
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 stor- age conditions	:	Recommended storage temperature: 5 - 25°C Protect from 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/m3	GB EH40	
	Further inform	nation: Where no spe	cific short-term exposure lim	it is listed, a	
	figure three tir	mes the long-term ex	posure limit should be used.		
		TWA (Total va-	150 ppm	GB EH40	
		pour and parti-	474 mg/m3		
		cles)			
	Further inform	nation: Where no spe	ecific short-term exposure lim	it is listed, a	
	figure three tir	mes the long-term e>	posure limit should be used.		
glycerol	56-81-5	TWA (Mist)	10 mg/m3	GB EH40	
	Further inform	nation: Where no spe	ecific short-term exposure lim	it is listed, a	
	figure three tir	mes the long-term e>	posure limit should be used.		
2-aminoethanol	141-43-5	TWA	1 ppm	2006/15/EC	
			2.5 mg/m3		
	Further information: Indicative, Identifies the possibility of significant uptake				
	through the sl	kin			
		STEL	3 ppm	2006/15/EC	
			7.6 mg/m3		
	Further inform	nation: Indicative, Ide	entifies the possibility of signif	icant uptake	
	through the sl	kin			
		TWA	1 ppm	GB EH40	
			2.5 mg/m3		
	Further inform	nation: Can be absor	bed through the skin. The as	signed sub-	
	stances are those for which there are concerns that dermal absorption will				
	lead to systen	nic toxicity.			
		STEL	3 ppm	GB EH40	
			7.6 mg/m3		
	Further inform	nation: Can be absor	bed through the skin. The as	signed sub-	
	stances are those for which there are concerns that dermal absorption will				

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	lead to syster	nic toxicity.			
subtilisin	9014-01-1	TWA	0.00004 mg/m3	GB EH40	)
	Further inform	nation: One of the	e suitable measureme	nt methods is the fluc	ores-
	cence polaris	ation technique c	leveloped by the Healt	h and Safety Laborat	tory
	(HSL). The pr	evious limit for s	ubtilisin was based on	high-volume static s	am-
	pling to achie	ve sufficient sens	sitivity. However, impro	ovements in the analy	/tical
	methodology	have improved th	he sensitivity and the V	VEL for subtilisin refle	ects
	this. The limit	is based on stan	dard personal samplin	ig (MDHS14/4).4 Sho	ort-
	term referenc	e period (15 mini	ute) sampling is not ap	propriate., Substanc	es
	that can caus	e occupational a	stnma (also known as	asthmagens and res	pira-
	tory sensitise	rs) can induce a s	state of specific airway	nyper-responsivene	SS bo
	via an immun	ological initiant of	rother mechanism. Or	ice the alrways have	be-
	come nyper-n	esponsive, iurthe	er exposure to the subs	stance, sometimes ev	ven
	rango in covo	rity from a ruppy	espiratory symptoms.	I hese symptoms car	I V
	nosed to a se	ncy norn a runny	me hyper-responsive :	and it is impossible to	x- >
	identify in adv	ance those who	are likely to become b	vnor-rosnonsivo Si	, ub-
	stances that (		ational asthma should	he distinguished from	n n
	substances w	hich may trigger	the symptoms of asth	na in people with pre	- ۱
	existing airwa	iv hyper-responsi	iveness, but which do	not include the disea	se
	themselves.	The latter substar	nces are not classified	as asthmagens or re	espir-
	atory sensitis	ers. Further infor	mation can be found ir	the HSE publication	۰ ۱
	Asthmagen?	Critical assessme	ents of the evidence fo	r agents implicated in	n
	occupational	asthma., Wherev	er it is reasonably prac	cticable, exposure to	sub-
	stances that of	can cause occupa	ational asthma should	be prevented. Where	e this
	is not possible	e, the primary ain	n is to apply adequate	standards of control	to
	prevent worke	ers from becomin	ig hyper-responsive. F	or substances that ca	an
	cause occupa	ational asthma, C	OSHH requires that ex	posure be reduced t	o as
	low as is reas	onably practicab	le. Activities giving rise	e to short-term peak	con-
	centrations sh	nould receive par	ticular attention when	risk management is t	being
	considered. H	lealth surveillanc	e is appropriate for all	employees exposed	or
	liable to be ex	(posed to a subs	tance which may caus	e occupational astnm	1a
	and there sho	ouid be appropria	te consultation with an	occupational nealth	pro-
	techutic on tur	r the degree of h	Realling subtilia They	ance., Subulisins are	pro-
	washing now	dere animal food	bacilius subuils. They	are used in biologica	
	active enzym	e inactive enzym	and protein residues	Canable of causin	.s
	occupational	asthma Where	no specific short-term	exposure limit is liste	ыdа
	figure three ti	mes the long-terr	n exposure limit shoul	d be used. The 'Sen'	u, u '
	notation in the	e list of WELs has	s been assigned only t	o those substances	which
	may cause or	cupational asthn	na in the categories sh	own in Table 1. It sh	ould
	be remember	ed that other sub	stances not in these ta	ables may cause occ	upa-
	tional asthma	. HSE's asthma	web pages (www.hse.g	ov.uk/asthma) provi	de
	further inform	ation.		· / ·	

	· · ·	0 0	· · /	
Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
propane-1,2-diol	Workers	Inhalation	Long-term systemic	168 mg/m3
			effects	
	Workers	Inhalation	Long-term local ef-	10 mg/m3
			fects	
sodium p-	Workers	Skin contact	Long-term systemic	136.25 mg/kg
cumenesulphonate			effects	
	Workers	Skin contact	Long-term local ef-	0.096 mg/cm2

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Z11276 ZSDB\_P\_GB EN

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			fects	
	Workers	Inhalation	Long-term systemic effects	26.9 mg/m3
2-aminoethanol	Workers	Skin contact	Long-term systemic effects	1 mg/kg
	Workers	Inhalation	Long-term local ef- fects	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	2000 ppm
	Workers	Inhalation	Long-term local ef- fects	0.00006 mg/m3

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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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
	Soil	50 mg/kg
sodium p-cumenesulphonate	Fresh water	0.23 mg/l
	Marine water	0.023 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	0.862 mg/kg
	Marine sediment	0.0862 mg/kg
	Soil	0.037 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	0.425 mg/kg
	Marine sediment	0.0425 mg/kg
	Soil	0.035 mg/kg
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 protection

: Safety glasses with side-shields conforming to EN166

Hand protection

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Directive	:	The selected protective gloves have to satisfy the specifica- tions 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. Pro- longed 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 protec- tion.
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	No personal respiratory protective equipment normally re- quired.
Protective measures	:	Avoid contact with skin and eyes.

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## **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
рН	:	11 (20 °C) Concentration: 100 %
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
Flammability (solid, gas) Upper explosion limit / Upper flammability limit	:	Not applicable No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available





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Vapour d	ensity	:	No data available
Relative	density	:	ca. 1.10 g/cm3 (20 °C, 1,013 hPa)
Solubility Water	(ies) · solubility	:	completely soluble (20 °C)
Partition octanol/w	coefficient: n- /ater	:	Not applicable
Auto-igni	tion temperature	:	No data available
Viscosity Viscos	sity, dynamic	:	ca. 9 mPa*s Method: ISO 3219
Explosive	e properties	:	No data available
Oxidizing	properties	:	No data available
9.2 Other info	ormation		
Flammab	ility (liquids)	:	Does not sustain combustion.
			-14

#### **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
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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

#### Product:



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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
<u>Comp</u>	onents:		
sodiu	m p-cumenesulphona	te:	
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-ami	noethanol:		
Acute	oral toxicity	:	(Rat): 1,515 mg/kg Method: OECD Test Guideline 401 Assessment: Harmful if swallowed.
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. Remarks: No data available
sodiu	m 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
Alcoh	ols, C12-15-branched	and	l linear, ethoxylated propoxylated:
Acute	oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: Calculated value
Acute	inhalation toxicity	:	Remarks: not determined
Acute	dermal toxicity	:	Remarks: not determined

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Acute or	al toxicity :	LD50 (Rat): 1,800 mg/kg Method: OECD Test Guideline 401
Acute de	ermal toxicity :	Remarks: No data available
Skin cor	rosion/irritation	
<b>Product</b>	<u>:</u>	
Remarks	3 :	Causes skin irritation.
Compor	nents:	
sodium	p-cumenesulphonate:	
Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result		slight irritation
Remarks	3	Based on available data, the classification criteria are not met.
2-amino	ethanol:	
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
Alcohol	s, C12-15-branched an	d linear, ethoxylated propoxylated:
Species	:	Rabbit
Method	:	Draize Test
Result	:	Skin irritation
subtilisi	n:	
Method	:	OECD Test Guideline 404
Result	:	Skin irritation
Serious	eye damage/eye irrita	tion
<b>Product</b>	<u>:</u>	
Remarks	s :	Causes serious eye irritation.
Compor	nents:	
sodium	p-cumenesulphonate:	
Species		Rabbit
Method	:	OECD Test Guideline 405
Result	:	Eye irritation



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2-aminooth	anol	
Species		Rabbit OECD Test Guideline 405
Result	•	Risk of serious damage to eves
Result		Nisk of schous damage to cycs.
sodium etas	sulfate:	
Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Irreversible effects on the eye
Alcohols, C	12-15-branched an	nd linear, ethoxylated propoxylated:
Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation
subtilisin:		
Method	:	OECD Test Guideline 405
Result	:	irreversible effects on the eye
Respiratory	or skin sensitisati	ion
<u>Component</u>	<u>s:</u>	
sodium p-ci	umenesulphonate:	
Test Type	•	Buehler Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitisation on laboratory animals.
2-aminoetha	anol:	
Test Type	:	Maximisation Test
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitisation on laboratory animals.
sodium etas	sulfate:	
Method	:	OECD Test Guideline 429
Result	:	Did not cause sensitisation on laboratory animals.
Alconois, C	12-15-branched an	id linear, ethoxylated propoxylated:
Kemarks	:	IND GATA AVAIIADIE
subtilisin:		
Result	:	Probability of respiratory sensitisation in humans based on
		animal testing
Remarks	:	largely based on human evidence



#### thermosept® X-tra No Change Service! Version **Revision Date:** Date of last issue: 28.02.2020 04.04 19.10.2020 Date of first issue: 03.04.2012 Germ cell mutagenicity **Components:** sodium p-cumenesulphonate: Genotoxicity in vitro Test Type: Mutagenicity (Salmonella typhimurium - reverse 2 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- As-	:	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- As- sessment	:	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)
	Test system: Bacteria
	Method: OECD Test Guideline 471
	Result: negative
	C C

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

Genotoxicity in vitro	:	Test Type: Microbial mutagenesis assay (Ames test) Result: negative
Germ cell mutagenicity- As- sessment	:	Based on available data, the classification criteria are not met.
subtilisin:		
Genotoxicity in vitro	:	Method: OECD Test Guideline 471 Result: Non mutagenic
Germ cell mutagenicity- As- sessment	:	Animal testing did not show any mutagenic effects.



#### thermosept® X.tra No Change Service! Version **Revision Date:** Date of last issue: 28.02.2020 04.04 19.10.2020 Date of first issue: 03.04.2012 Carcinogenicity **Components:** sodium p-cumenesulphonate: Species Rat 5 Exposure time : 2 Years Method : **OECD** Test Guideline 453 Result : no increase in tumors observed Carcinogenicity - Assess-: Animal testing did not show any carcinogenic effects. ment 2-aminoethanol: Carcinogenicity - Assess-: Not classifiable as a human carcinogen. ment 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 - Assess-Weight of evidence does not support classification as a car-: cinogen ment subtilisin: Carcinogenicity - Assess-No data available : ment **Reproductive toxicity 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 develop-Species: Rat ment Application Route: Oral General Toxicity Maternal: NOAEL: 936 mg/kg body weight Teratogenicity: NOAEL: 936 mg/kg bw/day Reproductive toxicity - As-: study scientifically unjustified sessment Based on available data, the classification criteria are not met.

#### 2-aminoethanol:

according to Regulation (EC) No. 1907/2006



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Effects	s 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.
Repro- sessm	ductive toxicity - As- : ent	Based on available data, the classification criteria are not met. Animal testing did not show any effects on foetal develop- ment.
sodiu	m etasulfate:	
Effects	s on foetal develop- :	Species: Rat Application Route: Oral Dose: 250 milligram per kilogram Result: negative Remarks: Did not show teratogenic effects in animal experi- ments.
Repro- sessm	ductive toxicity - As- : ent	No data available
Alcoh	ols, C12-15-branched and	d linear, ethoxylated propoxylated:
Repro- sessm	ductive toxicity - As- : ent	Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.
subtil	isin:	
Repro- sessm	ductive toxicity - As- : ent	No data available No data available
STOT	- single exposure	
<u>Comp</u>	onents:	
sodiu	m p-cumenesulphonate:	
Asses	sment :	The substance or mixture is not classified as specific target organ toxicant, single exposure.
2-amii	noethanol:	
Asses	sment :	May cause respiratory irritation.
sodiu	m etasulfate:	
Rema	rks :	No data available
Alcoh	ols, C12-15-branched and	d linear, ethoxylated propoxylated:
Rema	rks :	No data available



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subtilisin:			
Target Organs	: Respiratory Tract		
Assessment	: May cause respiratory irritation.		
STOT - repeated exposure			
Components:			
sodium p-cumenesulphonate	<b>a</b> .		
Assessment	<ul> <li>The substance or mixture is not classified as specific target</li> </ul>		
/ loocooment	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 a	nd linear. ethoxylated propoxylated:		
Remarks	No data available		
Repeated dose toxicity			
Components:			
sodium p-cumenesulphonate	<b>.</b>		
	· 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 year		
Method	: OECD Test Guideline 453		
Target Organs	: Skin		
sodium etasulfate:			
Species	· Rabbit		
NOAEL	: 488 mg/kg		
Application Route	: Oral		
Exposure time	: 90-day		
Number of exposures	: 7 Tage pro Woche		
Species	: Mouse		
NOAEL	: 400 mg/kg		
Application Route	: Skin contact		
Exposure time	: 90-day		

according to Regulation (EC) No. 1907/2006



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Number	of exposures	: 2 Tage pro Woche
Aspiratio	on toxicity	
<u>Compon</u>	ents:	
Alcohols	e viscosity, this produ	nd linear, ethoxylated propoxylated: ct does not present an aspiration hazard. sure
<u>Compon</u>	ents:	
2-aminoe	ethanol:	
General I	nformation	: Repeated and prolonged exposure to solvents may cause brain and nervous system damage.
Further i	nformation	
Product:		

Remarks

: The product has not been tested.

## **SECTION 12: Ecological information**

### 12.1 Toxicity

sodium p-cumenesul	phonate:	
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and aquatic invertebrates	d other :	EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquat plants	ic :	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 Method: Tested according to Directive 92/69/EEC.
Toxicity to daphnia and aquatic invertebrates	d other :	EC50 (Daphnia magna): 65 mg/l Exposure time: 48 h Method: EG 84/449
Toxicity to algae/aquat plants	ic :	EC50 (Scenedesmus capricornutum (fresh water algae)): 2.5 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

according to Regulation (EC) No. 1907/2006



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Т ic Т	oxicity to fish (Chronic tox- ity) oxicity to daphnia and other	:	1.2 mg/l Exposure time: 30 d Species: Oryzias latipes (Orange-red killifish) NOEC: 0.85 mg/l
a ic	quatic invertebrates (Chron- toxicity)		Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
S	odium etasulfate:		
T	oxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h
T a	oxicity to daphnia and other quatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 483 mg/l Exposure time: 48 h
Т р	oxicity to algae/aquatic lants	:	EC50 (Desmodesmus subspicatus (green algae)): > 511 mg/l Exposure time: 72 h
Т ic	oxicity to fish (Chronic tox- ity)	:	NOEC: >= 1,357 mg/l Exposure time: 42 d Species: Pimephales promelas (fathead minnow)
T a ic	oxicity to daphnia and other quatic invertebrates (Chron- toxicity)	:	NOEC: 1.4 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
Δ	Icohols C12-15-branched	and	l linear, ethoxylated propoxylated:
	oxicity to fish	:	LC50 (Leuciscus idus): 1 - 10 mg/l Exposure time: 96 h
T a	oxicity to daphnia and other quatic invertebrates	:	EC50 (Daphnia magna): 0.1 - 1 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Т р	oxicity to algae/aquatic lants	:	EC50 (algae): 0.1 - 1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
N ic	I-Factor (Acute aquatic tox- ity)	:	1
T a ic	oxicity to daphnia and other quatic invertebrates (Chron- toxicity)	:	NOEC: > 0.1 - < 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea)
s	ubtilisin:		
ľ	oxicity to fish	:	LC50 (Fish): 8.2 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Т	oxicity to daphnia and other	:	EC50 (Daphnia magna): 0.586 mg/l



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aq	uatic invertebrates	Exposure time: 48 h Method: OECD Test Guideline 202
To pla	xicity to algae/aquatic : ants	ErC50 (algae): 0.83 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M- icit	Factor (Acute aquatic tox- :	1
To icit	xicity to fish (Chronic tox- : y)	NOEC: 0.017 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
M- tox	Factor (Chronic aquatic : kicity)	1
12.2 Pe	ersistence and degradability	
Pro	oduct:	
Bic	odegradability :	Result: Readily biodegradable, according to appropriate OECD test. Method: OECD 301D / EEC 84/449 C6
<u>Co</u>	omponents:	
so	dium p-cumenesulphonate:	
Bic	odegradability :	Test Type: aerobic Result: Readily biodegradable. Biodegradation: > 60 % Exposure time: 28 d Method: OECD Test Guideline 301B
2-a	aminoethanol:	
Bic	odegradability :	Test Type: aerobic Inoculum: activated sludge Result: Readily biodegradable. Biodegradation: > 90 % Exposure time: 21 d Method: OECD Test Guideline 301A
so	dium etasulfate:	
Bic	odegradability :	Result: Readily biodegradable. Biodegradation: 89 % Exposure time: 28 d Method: OECD Test Guideline 301B
Ale	cohols, C12-15-branched and	l linear, ethoxylated propoxylated:
Bio	odegradability :	Result: Readily biodegradable. Biodegradation: > 60 % Exposure time: 28 d





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			Method: OECD Test Guideline 301B
sub	otilisin:		
Bio	degradability	:	Result: Readily biodegradable. Method: OECD Test Guideline 301B
12.3 Bic	accumulative potential		
<u>Co</u>	nponents:		
soc	lium p-cumenesulphona	te:	
Bio	accumulation	:	Remarks: Bioaccumulation is unlikely.
2-a	minoethanol:		
Bio	accumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Par octa	tition coefficient: n- anol/water	:	log Pow: -1.91
soc	lium etasulfate:		
Bio	accumulation	:	Remarks: No data available
Par octa	tition coefficient: n- anol/water	:	log Pow: -0.248
Alc	ohols, C12-15-branched	and	linear, ethoxylated propoxylated:
Bio	accumulation	:	Remarks: Accumulation in aquatic organisms is unlikely.
sub	otilisin:		
Bio	accumulation	:	Remarks: Does not bioaccumulate.
Par octa	tition coefficient: n- anol/water	:	log Pow: < 0
∎ 12.4 Mo	bility in soil		
<u>Co</u>	nponents:		
soc	lium p-cumenesulphona	te:	
Mol	oility	:	Remarks: Not expected to adsorb on soil.
2-a	minoethanol:		Demorker Net expected to edecite an acit
IVIO	onity	:	Remarks: Not expected to adsorb on Soll.
soc	lium etasulfate:		
Mol	oility	:	Remarks: No data available

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



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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	
12.5 Results of F	PBT and vPvB ass	ses	sment	
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	
12.6 Other adver	se effects			
Product:				
Additional ec mation	ological infor-	:	No data is available on the product itself.	
SECTION 13: D	isposal conside	era	tions	
13.1 Waste treat	13.1 Waste treatment methods			

Product	:	Dispose of the product according to the defined EWC (European Waste Code) No.
Contaminated packaging	:	Take empty packaging to the recycling plant.
Waste key for the unused product	:	European waste catalog (EWC) 070601*
Waste key for the unused product(Group)	:	Waste material of HZVA from fats, lubricants, soaps, deter- gents, disinfectants and personal protection products.

#### **SECTION 14: Transport information**

#### 14.1 UN number

Not regulated as a dangerous good

#### 14.2 UN proper shipping name

Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

#### 14.4 Packing group

Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

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#### 14.6 Special precautions for user

Not applicable For personal protection see section 8.

#### 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

:	Conditions of restriction for the fol- lowing entries should be considered: Number on list 3
:	Not applicable
	: : : :

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. 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: 3.72 %
Regulation (EC) No. 648/2004, as amended	:	5 % or over but less than 15 %: Anionic surfactants less than 5 %: Non-ionic surfactants, Polycarboxylates Other constituents: Enzymes

#### Other regulations:

The surfactant(s) contained in this mixture complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure



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limit values.

#### 15.2 Chemical safety assessment

Exempt

#### **SECTION 16: Other information**

Harmful if swallowed.
Harmful in contact with skin.
Causes severe skin burns and eye damage.
Causes skin irritation.
Causes serious eye damage.
Causes serious eye irritation.
Harmful if inhaled.
May cause allergy or asthma symptoms or breathing difficul- ties if inhaled.
May cause respiratory irritation.
Very toxic to aquatic life.
Toxic to aquatic life with long lasting effects.
Harmful to aquatic life with long lasting effects.
Acute toxicity
Short-term (acute) aquatic hazard
Long-term (chronic) aquatic hazard
Serious eye damage
Eye irritation
Respiratory sensitisation
Skin corrosion
Skin irritation
Specific target organ toxicity - single exposure
Europe. Indicative occupational exposure limit values
UK. EH40 WEL - Workplace Exposure Limits
Limit Value - eight hours
Short term exposure limit
Long-term exposure limit (8-hour TWA reference period) Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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 Mari

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time 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### Further information

Classification of the mixture:		Classification procedure:	
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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