AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
						mayr	endo			
DM000305512	AGENT DE CURĂȚARE	THERMOSEPT®	X-TRA	127604	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021	
DM000303257	DEZINFECTANT PENTRU INSTRUMENTE MEDICALE	THERMOSEPT® ED			Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000041	14-02-2021	
DM000262085	AGENT DE CURĂȚARE	THERMOSEPT®	X-TRA		Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000331	18-12-2019	

Содержит([Reprezentant], 'endo') И Содержит([Producatorul], 'mayr') И ([NameMake] Равно...

Очисти

Digitally signed by Dubalari Pavel
Date: 2021.05.07 08:28:23 EEST
Reason: MoldSign Signature
Location: Moldova

Declaration of Conformity

schülke

EC declaration of conformity

Manufacturer according to Regulation 2017/745	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany
Registration Number acc. to Art. 31 2017/745	not issued so far
Product name	**thermosept® X-tra**
basic UDI-DI	4032651-BSC00000004-CT
Code acc. to Art. 26 2017/745	V07
Intended Purpose	cleaning agent for automated reprocessing of medical devices
Risk Class according to Regulation 2017/745	I annex VIII rule 1
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH
Conformity Assessment Procedure according to Regulation 2017/745	annex IV / V
Certificate	EN ISO 13485 004567 MP2016
Version	1-0

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Regulation 2017/745 concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt

ppa.

Dr. Uwe Berlekamp

17. FEB. 2021

Dr. Uwe Berlekamp
Schülke & Mayr GmbH
Director Business Lines, Research & Regulatory Affairs

ppa.

Dr. Thorsten August
Schülke & Mayr GmbH
Director Global Quality & Health, Safety, Environment

This Declaration is valid until an updated version has been issued, but not longer than 18.12.2021

Declaration of Conformity

schülke

EC declaration of conformity

Medical Device name	**thermosept® ED**
Formulation No.	F06
Product group	Disinfectant, medical device instruments
Product Category	05 - Hospital hardware
Intended Purpose	instrument disinfection
Risk Class according to Directive 93/42/EEC annex	II b IX
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs
Manufacturer according to Directive 93/42/EEC	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297
Conformity Assessment Procedure according to Council Directive 93/42/EEC	Annex II excluding section 4
Issued Certificates	Annex II 93/42/EEC Cert. Reg. No. 004567 MR2
Version	1.0

Schülke & Mayr GmbH herewith declares that the device covered by this declation is in conformity with the Council Directive 93/42/EEC concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt 15.04.2020

ppa. Dr. Uwe Berlekamp
Schülke & Mayr GmbH
Director Business Lines, Research & Regulatory Affairs

15.04.2020

ppa. Dr. Thorsten August
Schülke & Mayr GmbH
Director Global Quality & Health, Safety, Environment

This Declaration is valid until an updated version has been issued, but not longer than 18.12.2023

CERTIFICATE

This is to certify that

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Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and sales of products for hygiene, body care and preservation.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Certificate registration no.	004567 QM15
Certificate unique ID	170730583
Effective date	2018-12-19
Expiry date	2021-11-17
Frankfurt am Main	2018-12-19

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-02-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

401.99 Version 2.0

Annex to certificate
Certificate registration No.: 004567 QM15
Certificate unique ID: 170730583
Effective date: 2018-12-19

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schülke & Mayr GmbH Robert-Koch-Straße 2 22851 Norderstedt Germany	Development, production and sales of products for hygiene, body care and preservation.
Schülke & Mayr AG Sihlfeldstrasse 58 8003 Zürich Switzerland	Sales of products for hygiene, body care and preservation.
Schülke & Mayr Ges. m. b. H. Seidengasse 9 1070 Wien Austria	Sales of products for hygiene, body care and preservation.
Schülke & Mayr GmbH Altenhöfer Allee 5 60438 Frankfurt Germany	Sales of products for hygiene, body care and preservation.
Schülke France S.A.R.L. 22, Terrasse Bellini Paris La Defense 92800 Puteaux Cedex France	Sales of products for hygiene, body care and preservation.
Schülke & Mayr UK Ltd. Cygnet House, 1 Jenkin Road, Meadowhall Sheffield, S9 1AT United Kingdom	Sales of products for hygiene, body care and preservation.

Annex to certificate
Certificate registration No.: 004567 QM15
Certificate unique ID: 170730583
Effective date: 2018-12-19

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schülke & Mayr Italia S.R.L. Via Calabria, 31 20158 Milano Italy	Sales of industrial preservatives, products of hygiene for industrial production facilities and special additives for the cosmetic industry.
Schülke & Mayr Benelux B.V. Oudeweg 8d 2031 CC Haarlem Netherlands	Sales of products for hygiene, body care and preservation.
Schulke Polska Sp. z o.o. Eurocentrum Office Complex, Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland	Sales of products for hygiene, body care and preservation.

CERTIFICATE

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	004567 MP2016
Certificate unique ID	170732268
Effective date	2019-03-30
Expiry date	2021-12-18
Frankfurt am Main	2019-03-30

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170732268
Effective date: 2019-03-30

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schülke & Mayr GmbH Robert-Koch-Straße 2 22851 Norderstedt Germany	Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr AG Sihlfeldstrasse 58 8003 Zürich Switzerland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Ges. m. b. H. Seidengasse 9 1070 Wien Austria	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr GmbH Altenhöfer Allee 5 60438 Frankfurt Germany	Development and sales of products for disinfection and cleaning of medical instruments, devices and surfaces.
Schülke France S.A.R.L. 22, Terrasse Bellini Paris La Defense 92800 Puteaux Cedex France	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr UK Ltd. Cygnet House, 1 Jenkin Road, Meadowhall Sheffield, S9 1AT United Kingdom	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
Schülke & Mayr Benelux B.V. Oudeweg 8d 2031 CC Haarlem Netherlands	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170732268
Effective date: 2019-03-30

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
Schulke Polska Sp. z o.o. Eurocentrum Office Complex Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

schülke

thermosept® ED in combination with the cleaning agent thermosept® ER or thermosept® alka clean forte offers comprehensive cleaning and aldehyde disinfection for chemo-thermal reprocessing of flexible endoscopes.

CE

thermosept® ED

Our plus:

- virucidal, sporicidal
- comprehensive microbiological efficacy
- excellent material compatibility
- foam-free

Application methods / Instructions for use

Flexible endoscopes and additional endoscopic equipment can be reprocessed either using aldehyde-free or aldehyde-based products.

thermosept® ED containing aldehyde is intended for the combination of thermosept® ER or thermosept® alka clean forte.

All products are foam-inhibited and enable using cold or warm water in every step of the programme with orderly function.

thermosept® ER and thermosept® ED are compatible.

Microbiological efficacy

The microbiological efficacy of thermosept® ED has been tested by experts under machine-specified conditions (time/temperature).

• bactericidal (incl. M. terrae) • Helicobacter pylori • fungi
• enveloped (incl. HIV, HBV, HCV) • adeno and papova virus
• virucidal • spores* C.Diff. Ribo 027 • round worm eggs*

* at 60 °C – 1 % – 5 min. + 1 min. heating up, C. diff. 1 % – 15 min., 60 °C

Application concentration / Contact time

The product is dosed by means of machine-integrated pumps.

thermosept® ED: from 1 % – 5 minutes – 55 °C

Product data

Ingredients:
100 g thermosept® ED contain: 20 g glutaraldehyde

Further ingredients: corrosion inhibitors, solubilisers, complexing agents.

Chemical-physical data:

Concentrate:	
Appearance:	colourless liquid
Density (20 °C):	1.04 g/cm³
pH-value:	3.6
1 % stock solution:	
Appearance:	clear solution
pH-value:	approx. 7

Labelling according to EC directives

C:	Corrosive.
R20/22:	Harmful by inhalation and if swallowed.
R34:	Causes burns.
R42/43:	May cause sensitisation by inhalation and skin contact.
S23:	Do not breathe vapour.
S26:	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39:	Wear suitable protective clothing, gloves and eye/face protection.
S45:	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
S51:	Only use in well-ventilated areas.

thermosept® ED

Product liability

thermosept® ED was thoroughly tested for its application and microbiology. It is suitable, among others, for devices of the manufacturers BHT, Hamo, Kleindienst and Olympus e.g. (Innova; SME; WS; ETD series).

Thus, we confirm that within the scope of the German Product Liability Law, we are liable for all damage that has demonstrably been caused by deficiencies of our preparations when used for the above mentioned AER. The liability includes damage to the reprocessed endoscopes as well as to the above mentioned machines. A prerequisite is, among others, that our preparations are orderly applied, that the endoscopes have not been damaged before and that the machines work flawlessly.

Environmental information

schülke produces its products according to advanced, safe and environmentally friendly procedures, economically and in compliance with high quality standards.

Expert opinions

Microbiology

Microbiological testing after installation of the Olympus Endo-Thermo disinfector ETD with THP 5917 (thermosept® ER) and TPH 5422 (thermosept® ED),
University Prof. J. R. Möse, MD, Graz, Austria, December 6, 1989

Virucidal activity of thermosept® ED against the poliovirus type I strain Mahoney,
Dr J. Steinmann, Bremen, Germany, November 10, 1991

Studies using the schülke products TPH 5917 (thermosept® ER) and TPH 5422 (thermosept® ED) in the ETD machine.
Part I: Microbiological studies,
U. Jürs, AK Barmbek, Hamburg, Germany, January 14, 1991

Studies on the efficacy of thermosept® ED against mycobacteria, *Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germany, August 10, 1992*

Study on sporicidal efficacy of the instrument disinfectant thermosept® ED, *Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germany, April 22, 1994*

Expert opinion on the testing of disinfectants applied to parasitic dauer stages, *Dr R. Böse, Prof. K. T. Friedhoff, Hannover, Germany, July 5, 1994*

Study on the efficacy against the hepatitis-B-virus (HBV) of the chemical disinfectant thermosept® ED, *G. Schwalbach, MD, Bad Mergentheim, Germany, November 14, 1994*

In-hospital evaluation of BHT INNOVA 2000 Washer/Disinfector for Processing of Flexible Endoscopes,
Prof. Sattar, Ottawa/Canada, May 1996

Bacteriological study on the endoscopes washer BHT Innova E3 with thermosept® ER/ED,
Manfred P. Dierich, MD, Innsbruck, Austria, February 24, 1998

Hygienic-microbiological test in BHT Innova E3 with thermosept® ER/ED, *Mag. Dr T. Miorini, Graz, Austria, September 1999*

Study on the efficacy of thermosept® ED against poliovirus,
Dr J. Steinmann, Bremen, Germany, June 4, 1999

Disinfecting efficacy of thermosept® ED against Heliobacter pylori, *Prof. W. Solbach, MD, Lübeck, Germany, February 20, 1998*

Efficacy of thermosept® ED against the Bovine Viral Diarrhea Virus (BVDV) in a quantitative suspension test at 50 °C,
Dr J. Steinmann, Bremen, Germany, July 2004

Efficacy of thermosept® AF against the adeno virus in a quantitative suspension test at 50 °C,
Dr J. Steinmann, Bremen, Germany, August 2004

Efficacy of thermosept® ED against the papova virus SV 40 in a quantitative suspension test at 50 °C,
Dr J. Steinmann, Bremen, Germany, August 2004

Efficacy of thermosept® ED against the vaccinia virus in a quantitative suspension test at 50 °C,
Dr J. Steinmann, Bremen, Germany, November 2004

Efficacy of thermosept® ED against the parvovirus in a quantitative suspension test at 55 °C according to EN 14476:2007-02,
Dr J. Steinmann, Bremen, Germany, February 2009

Efficacy of thermosept® ED against Clostridium difficile (ribotype 027), *Prof. M. Exner, MD, Bonn, Germany, January 12, 2009*

Compatibility of materials

Studies on the compatibility of materials with TPH 5917 (thermosept ® ER) and TPH 5422 (thermosept® ED),
M. Mohr, schülke Research and Development, Norderstedt, Germany, December 15, 1989

Studies using the schülke products TPH 5917 (thermosept ® ER) and TPH 5422 (thermosept® ED) in the ETD machine,
Part II: Application-technological studies,
H. Menzel, AK Barmbek, Hamburg, Germany, January 14, 1991

Suitability of thermosept® products for the BHT- ERD device, BHT,
H. Biermaier, Friedberg-Derching, Germany, October 27, 1992

Biodegradability

thermosept® ED: Biodegradability according to OECD test specification 301, *Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germany, March 28, 1991*

Schülke & Mayr GmbH is certified according to DIN EN ISO 9001, DIN EN ISO 14001 and DIN EN ISO 13485 **(Reg.-No. 004567-MP23)** and has a validated environmental system in accordance with the Eco Audit Regulation **(Reg.-No. DE-150-00003)**.

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2295 / II / 03.11 / B / westwerk

schülke

thermosept® ED, în combinaţie cu agentul de curăţare thermosept® ER sau thermosept® alka clean forte, asigură o curăţare completă şi o dezinfecţie aldehidică pentru reprocesarea chimico-termică a endoscoapelor flexibile.

CE

thermosept® ED

Avantajul nostru:

- ucide viruşii şi sporii;
- eficacitate microbiologică completă;
- compatibilitate excelentă cu materialele;
- nu formează spumă

Metode de aplicare / Instrucţiuni de utilizare

Endoscoapele flexibile şi alte echipamente endoscopice pot fi reprocesate utilizând fie produşi fără aldehide, fie produşi pe bază de aldehide.

thermosept® ED, care conţine aldehide, este destinat pentru utilizare în combinaţie cu thermosept® ER sau thermosept® alka clean forte.

Aceste produse nu formează spumă şi permit utilizarea apei calde sau reci în fiecare etapă a programului cu funcţia normală.

thermosept® ER şi thermosept® ED sunt compatibile.

Eficacitatea microbiologică

Eficacitatea microbiologică a produsului thermosept® ED a fost testată de experţi în condiţii specificate (timp/temperatură) pe echipamente automate.

• bactericid (incl. M. terrae) • Helicobacter pylori • ciuperci
• virus încapsulat (incl. HIV, HBV, HCV) • adenovirus şi papovavirus
• virucidal • ucide sporii* C.Diff. Ribo 027 • ouă de viermi rotunzi*

* la 60 °C – 1 % – 5 min. + 1 min. încălzire, C. dif. 1 % – 15 min., 60 °C

Concentraţii utilizate / Timpul de contact

Produsul este dozat cu ajutorul pompelor integrate în aparat.

thermosept® ED: de la 1 % – 5 minute – 55 °C

Date privind produsul

Ingrediente:
100 g thermosept® ED conţin: 20 g glutaraldehidă

Alte ingrediente: inhibitori de coroziune, dizolvanţi, agenţi de complexare.

Date fizico-chimice:

Concentrat:	
Aspectul:	lichid incolor
Densitatea (20 °C):	1,04 g/cm³
Valoarea pH-ului:	3,6
soluţie-mamă de 1 %:	
Aspectul:	soluţie limpede
Valoarea pH-ului:	aproximativ 7

Etichetare conform directivelor CE

C:	Coroziv.
R20/22:	Nociv la inhalare şi în caz de ingerare.
R34:	Provoacă arsuri.
R42/43:	Poate cauza sensibilizare prin inhalare şi contactul cu pielea.
S23:	A nu se inhala vapori.
S26:	În cazul contactului cu ochii, clătiţi imediat cu multă apă şi solicitaţi asistenţă medicală.
S36/37/39:	Purtaţi îmbrăcăminte de protecţie adecvată, mănuşi şi protejaţi ochii/faţa.
S45:	În caz de accident sau dacă nu vă simţiţi bine, solicitaţi imediat asistenţă medicală (prezentaţi eticheta, dacă este posibil).
S51:	A se utiliza numai în locuri bine ventilate.

thermosept® ED

Răspunderea pentru produse

thermosept® ED a fost testat minuţios pentru utilizarea sa şi pentru microbiologie. Este adecvat, printre altele, pentru dispozitive ale producătorilor BHT, Hamo, Kleindienst şi Olympus (Innova; SME; WS; ETD).

Astfel, confirmăm că, în temeiul Legii germane privind răspunderea pentru produse, suntem responsabili pentru toate daunele cauzate în mod demonstrabil de deficienţe ale preparatelor noastre utilizate pentru scopul menţionat mai sus. Răspunderea include daunele provocate endoscoapelor reprocesate şi aparatelor menţionate mai sus. O precondiţie este, printre altele, că preparatele noastre sunt utilizate în mod normal, că endoscoapele nu au fost deteriorate anterior şi că aparatele funcţionează ireproşabil.

Informaţii de mediu

Produsele schülke sunt fabricate utilizând
procese avansate, sigure şi ecologice, în mod economic şi cu respectarea unor standarde de calitate înaltă.

Avize din partea experţilor

Microbiologie

Testare microbiologică după instalarea aparatului de dezinfecţie Olympus Endo-Thermo ETD cu THP 5917 (thermosept® ER) şi TPH 5422 (thermosept® ED),
Prof. univ. dr. J.R. Mose, Graz, Austria, 6 decembrie 1989

Acţiunea virucidă a thermosept® ED împotriva polivirusului tip I tulpina Mahoney,
Dr. J. Steinmann, Bremen, Germania, 10 noiembrie 1991

Studii privind utilizarea produselor schülke TPH 5917 (thermosept® ER) şi TPH 5422 (thermosept® ED) în aparatul ETD. Partea I: Studii de microbiologie,
U. Jürs, AK Barmbek, Hamburg, Germania, 14 ianuarie 1991

Studii privind eficacitatea thermosept®ED împotriva micobacteriilor,

Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germania, 10 august 1992

Studiu privind eficacitatea sporicidă a dezinfectantului pentru instrumente thermosept®ED,

Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germania, 22 aprilie 1994

Aviz al experţilor privind testarea dezinfectanţilor aplicaţi în etapele de dezvoltare a paraziţilor,

Dr R. Böse, Prof. K. T. Friedhoff, Hannover, Germania, 5 iulie 1994

Studiu privind eficacitatea dezinfectantului chimic thermosept® ED împotriva virusului hepatitei B (HBV),

G. Schwalbach, MD, Bad Mergentheim, Germania, 14 noiembrie 1994

Evaluare în spital a aparatului de spălare/dezinfecţie BHT INNOVA 2000 pentru procesarea endoscoapelor flexibile,
Prof. Sattar, Ottawa/Canada, mai 1996

Studiu bacteriologic privind aparatul de spălare a endoscoapelor BHT Innova E3 cu thermosept® ER/ED,
Manfred P. Dierich, MD, Innsbruck, Austria, 24 februarie 1998

Test igienico-microbiologic în aparatul BHT Innova E3 cu thermosept® ER/ED,
Mag. Dr T. Miorini, Graz, Austria, septembrie 1999

Studiu privind eficacitatea thermosept®ED împotriva poliovirusului,
Dr. J. Steinmann, Bremen, Germania, 4 iunie 1999

Eficacitatea de dezinfecţie a thermosept®ED împotriva Heliobacter pylori,
Prof. W. Solbach, MD, Lübeck, Germania, 20 februarie 1998

Eficacitatea thermosept® ED împotriva virusului diareei bovine (BVDV) într-o testare cantitativă a suspensiei la 50 °C,
Dr. J. Steinmann, Bremen, Germania, iulie 2004

Eficacitatea thermosept® ED împotriva adenovirusului într-o testare cantitativă a suspensiei la 50 °C,
Dr. J. Steinmann, Bremen, Germania, august 2004

Eficacitatea thermosept® ED împotriva papovavirusului SV 40 într-o testare cantitativă a suspensiei la 50 °C,
Dr. J. Steinmann, Bremen, Germania, august 2004

Eficacitatea thermosept® ED împotriva virusului variolei într-o testare cantitativă a suspensiei la 50 °C,
Dr. J. Steinmann, Bremen, Germania, noiembrie 2004

Eficacitatea thermosept® ED împotriva parvovirusului într-o testare cantitativă a suspensiei la 55 °C conform EN 14476:2007-02,

Dr. J. Steinmann, Bremen, Germania, februarie 2009

Eficacitatea thermosept® ED împotriva Clostridium difficile (ribotip 027), *Prof. M. Exner, MD, Bonn, Germania, 12 ianuarie 2009*

Compatibilitatea materialelor

Studii privind compatibilitatea materialelor cu TPH 5917 (thermosept® ER) şi TPH 5422 (thermosept® ED).
M. Mohr, schülke Research and Development, Norderstedt, Germania, 15 decembrie 1989

Studii privind utilizarea produselor schülke TPH 5917 (thermosept® ER) şi TPH 5422 (thermosept® ED) în aparatul ETD, Partea a II-a: Studii aplicativ-tehnologice,
H. Menzel, AK Barmbek, Hamburg, Germania, 14 ianuarie 1991

Adecvarea produselor thermosept® pentru dispozitivul BHT-ERD, BHT,
H. Biermaier, Friedberg-Derching, Germania, 27 octombrie 1992

Biodegradabilitatea

thermosept® ED: conform specificaţiei de testare OECD 301,

Dr P. Goroncy-Bermes, schülke Research and Development, Norderstedt, Germania, 28 martie 1991

Reprezentant autorizat în Republica Moldova:
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Adresa juridică: mun. Chișinău, str. Drumul Viilor 30/2, ap. 54, MD-2001;
Adresa fizică: mun. Chișinău, str. Meșterul Manole 9, MD-2023;
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e-mail: info@endochirurgie.md
web: www.endochirurgie.md

Schülke & Mayr GmbH este certifiicată conform DIN EN ISO 9001, DIN EN ISO 14001 şi DIN EN ISO 13485 **(Reg.-No. 004567-MP23)** şi are un sistem de mediu validat în conformitate cu Regulamentul
Auditului Ecologic **(Reg.-No. DE-150-00003)**.

Schülke & Mayr GmbH
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2295 / II / 03.11 / B / westwerk
Această informaţie despre produs nu este actualizată automat.

schülke

Mildly alkaline high performance cleaner for the automated reprocessing of medical devices

thermosept® X·tra

Our Plus

- excellent cleaning performance achieved by the synergistic combination of active substances of enzymes and surfactants
- low foaming formular
- optimized material compatibility, also suitable for anodized aluminium
- high economic efficiency due to low working concentration
- pH of >10 in the cleaning solution - risk reduction in the case of vCJK according to the recommendation of the German RKI (Robert-Koch Institute)
- silicate-free

Application areas

thermosept® X•tra is designed for the automated cleaning of medical devices and accessories e.g. surgical instruments, minimally invasive surgical instruments, including robotic instruments, materials used in anaesthesia, ophthalmological instruments, rigid endoscopes, containers and other instruments commonly used in the Central Sterile Supply Department. Product can be used in all common types of washer/disinfectors (WD) and tunnel/washers. The outstanding cleaning performance is based on the combination of an innovative system of detergents combined with high-performance enzymes. The activity of the special enzyme variant develops initially in the application solution - in this way, powerful performance is achieved directly in the cleaning phase in WD. Even at low doses, thermosept® X•tra removes organic contaminants such as blood, proteins, tissue residues as well as mucus and fatty impurities. The synergistic combination of active ingredients allow excellent compatibility with materials, even with sensitive materials such as anodized aluminum and non-ferrous metal. With a pH-value of >10, a ten-minute cleaning time and an elevated, non-protein-fixing process temperature during the cleaning phase, thermosept® X•tra contributes to risk reduction with regard to vCJK according to the German RKI recommendation. Released for the manual pretreatment and automated reprocessing of Intuitive Surgical® da Vinci robotic instruments.

Instructions for use

Dosage:
Standard concentration: 0.5 % (5 ml/l)
Depending on the degree of soiling: 0.3 - 1.0 % (3 - 10 ml/l)
Cleaning temperature standard: approx. 55°C (30 - 65 °C), cleaning time approx. 5 - 10 minutes
Cleaning indicators: All common indicators can be used.
Do not use thermosept® X•tra in combination with other products. The use of purified water is recommended. The neutralisation step required for classical alkaline cleaning agents is not necessary. When preparing ocular instruments, two interim rinsing steps with purified water before thermal disinfection are recommended or use neutraliser thermosept® NKZ. Dosing is performed by machine-integrated dosing pumps. Please note recommendations of machine and instrument manufacturers.

CE

thermosept® X·tra

Product data

Composition:
Labelling according to Regulation (EC) No. 648/2004: 5 - 15 % anionic surfactants, < 5 % nonionic surfactants, < 5 % polycarboxylate, enzymes.
Other ingredients: Solubiliser, corrosion inhibitors.

Chemical-physical data	
Color	yellow
Density	ca. 1,1 g/cm3 / 20 °C / 1.013 hPa
Flash point	> 100 °C / Method : DIN 51755 Part 1
Form	liquid
pH	ca. 11 / 20 °C / concentrate
Viscosity, dynamic	ca. 9 mPa*s / Method : ISO 3219

Special advice

Keep container tightly closed. Store at room temperature in the original container. Protect from frost, heat and sunlight. (Storage temperature: 5 - 25 °C).

Information for order

Item	Delivery form	Item no.
thermosept X·tra 200 l FA	1/drum(s)	on request
thermosept X·tra 5 l KA	1/Canister	on request
thermosept X·tra 10 l KA	1/Canister	on request
thermosept Xtra 20 l KA	1/Canister	on request
thermosept X-tra SOKA 5 l KA	1/Canister	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

Accessories

Accessories	Item no.
Can key for 5 + 10 l	135810

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining out high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: http://www.schuelke.com/. For individual questions: Customer Care Phone: +49 40 52100-666 E-Mail: info@schuelke.com

Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

A company of the Air Liquide-Group

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#2791 / 911290-WORLD-en-01-17 6/2016
This product information is not automatically updated.

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : THERMOSEPT ED

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

Use of the Substance/Mixture : Disinfectants

Recommended restrictions on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Producer/Supplier : Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt
Germany
Telephone: +4940521000
Telefax: +494052100318
mail@schuelke.com
www.schuelke.com

Contact person : Application Department HI
+49 (0)40/ 521 00 544 (Schülke UK +44 114 254 3500)
pab@schuelke.com

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

Emergency telephone number : +49 (0)40 / 52 100 –0

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (67/548/EEC, 1999/45/EC)

Harmful	R20/22: Harmful by inhalation and if swallowed.
Corrosive	R34: Causes burns.
Harmful	R42/43: May cause sensitization by inhalation and skin contact.

2.2 Label elements

Labelling according to EC Directives (1999/45/EC)

Hazard pictograms :

Corrosive

R-phrase(s)	:	R20/22	Harmful by inhalation and if swallowed.
		R34	Causes burns.
		R42/43	May cause sensitization by inhalation and skin contact.
S-phrase(s)	:	S23	Do not breathe vapour.
		S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
		S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.
		S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
		S51	Use only in well-ventilated areas.

In the EU, this product falls under the Directive medical devices 93/42/EEC.The product is classified and labelled in accordance with EC directives or respective national laws.

Hazardous components which must be listed on the label:
- 111-30-8 Glutaral

2.3 Other hazards

No special risks known.

3. Composition/information on ingredients

3.2 Mixtures

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

Hazardous components

Chemical Name	Index-Number CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
Glutaral	605-022-00-X 111-30-8 203-856-5 01-2119455549-XXXX	T; R23/25 C; R34 Xn; R42/43 N; R50	Acute Tox. 3; H301 Acute Tox. 3; H331 Skin Corr. 1B; H314 Resp. Sens. 1; H334 Skin Sens. 1; H317 Aquatic Acute 1; H400 Met. Corr. 1; H290	20 %
Ethanol	603-002-00-5 64-17-5 200-578-6 01-2119457610-	F; R11	Flam. Liq. 2; H225	5 - 15 %

	43-XXXX			

For the full text of the R-phrases mentioned in this Section, see Section 16.
For the full text of the H-Statements mentioned in this Section, see Section 16.

4. First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

If inhaled : Move the victim to fresh air and keep him calm.
No artificial respiration, mouth-to-mouth or mouth to nose. Use suitable instruments/apparatus.
If symptoms persist, call a physician.

In case of skin contact : Wash off immediately with plenty of water for at least 15 minutes.

In case of eye contact : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Obtain medical attention.

If swallowed : Do NOT induce vomiting.
Rinse mouth with water.
Give small amounts of water to drink.
Obtain medical attention.

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.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry powder
Foam
Water spray jet
Carbon dioxide (CO2)

Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.
Specific risk from the substance or the product itself, its combustion products or evolved gases	:	Fire may cause evolution of:, Carbon monoxide, Carbon dioxide (CO2)

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Ensure adequate ventilation. Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions	:	Do not flush into surface water.

6.3 Methods and materials 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 chapter 8 + 13

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	Avoid exceeding of the given occupational exposure limits (see section 8). Use only with adequate ventilation/personal protection.
Advice on protection against fire and explosion	:	No special protective measures against fire required.

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	:	Keep away from direct sunlight. Keep away from heat. Keep container tightly closed.
Advice on common storage	:	Keep away from food and drink.

7.3 Specific end use(s)

none

8. Exposure controls/personal protection

8.1 Control parameters

Components	CAS-No.	Value	Control parameters	Basis
Glutaral	111-30-8	TLV	0,05 ppm	ACGIH
Ethanol	64-17-5	Permissible exposure limit	500 ppm 960 mg/m3	TRGS 900
Ethanol	64-17-5	Ceiling Limit Value	1.000 ppm 1.920 mg/m3	TRGS 900
Ethanol	64-17-5	Permissible exposure limit	1.000 ppm 1.900 mg/m3	OSHA

8.2 Exposure controls

Personal protective equipment

Respiratory protection : Not required; except in case of aerosol formation.

Hand protection : 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.

Eye protection : Tightly fitting safety goggles

Hygiene measures : Keep away from food and drink.

Protective measures : Avoid contact with skin and eyes.
Do not breathe vapour.

Environmental exposure controls

General advice : Do not flush into surface water.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid
Colour : colourless
Odour : stinging

Flash point : 63 °C, DIN 51755 Part 1
Ignition temperature : Ethanol: > 360 °C
Lower explosion limit : Ethanol: 3,1 %(V)

Upper explosion limit	:	Ethanol: 15 %(V)
Flammability	:	Does not sustain combustion.
Explosive properties	:	no data available
Oxidizing properties	:	no data available
Auto-ignition temperature	:	not determined
pH	:	ca. 3,6, 20 °C, concentrate
Melting point/freezing point	:	< -5 °C
Decomposition temperature		no data available
Boiling point/boiling range	:	ca. 90 °C
Vapour pressure	:	ca. 35 hPa, 20 °C
Density	:	ca. 1,04 g/cm3, 20 °C
Water solubility	:	20 °C, in all proportions
Partition coefficient: n-octanol/water	:	not applicable
Viscosity, dynamic	:	ca. 3,2 mPa*s, 20 °C, DIN 53019
Relative vapor density	:	no data available
Evaporation rate	:	no data available

9.2 Other information

None known.

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

None reasonably foreseeable.

10.4 Conditions to avoid

Protect from frost, heat and sunlight.

10.5 Incompatible materials

Strong bases
Strong acids and oxidizing agents
Amines
Ammonia

10.6 Hazardous decomposition products

Decomposition products : None reasonably foreseeable.

11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity

Glutaral	:	LD50: 158 mg/kg, rat
Ethanol	:	LD50: 8300 mg/kg, mouse

Acute inhalation toxicity

Glutaral	:	LC50: 0,48 mg/l, 4 h, rat, Aerosol, OECD Test Guideline 403
Ethanol	:	LC50: 11200 mg/l, 1 h, mouse

Acute dermal toxicity

Glutaral	:	LD50: > 2000 mg/kg, rabbit
Ethanol	:	LD50: 20000 mg/kg, rabbit

Skin irritation	:	Classification: Causes burns.
Eye irritation	:	Classification: Causes burns.
Sensitisation	:	Practical experience:, May cause sensitization of susceptible persons.

Germ cell mutagenicity

Glutaral	:	Result: Conflicting results have been seen in different studies. Did not show mutagenic effects in animal experiments.
Ethanol	:	Result: Not mutagenic in Ames Test. , OECD Test Guideline 471

Genotoxicity in vivo

Ethanol	:	Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis), Result: not mutagenic

Mutagenicity

Glutaral	:	Did not show mutagenic effects in animal experiments.
Ethanol	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity

Glutaral	:	Animal testing did not show any carcinogenic effects.
Ethanol	:	Did not show carcinogenic effects in animal experiments.

Reproductive toxicity

Glutaral	:	Animal testing did not show any effects on fertility.
Ethanol	:	In animal testing, risk of impaired fertility was shown only after administration of very high doses of this substance.

Teratogenicity

Ethanol	:	rat, Oral, NOAEL: 2.000 mg/kg

Teratogenicity

Glutaral	:	Did not show teratogenic effects in animal experiments.
Ethanol	:	Animal experiments showed mutagenic and teratogenic effects.

Repeated dose toxicity

Glutaral	:	No adverse effect has been observed in chronic toxicity tests.
Ethanol	:	rat, Oral, NOAEL: 2.400 mg/kg

Further information	:	No data is available on the product itself. The classification was made according to the calculation procedure of the Preparations Directive.

12. Ecological information

12.1 Toxicity

Toxicity to fish

Glutaral	:	LC50: 9,4 mg/l, 96 h, Lepomis macrochirus (Bluegill sunfish)
Ethanol	:	LC50: 8.140 mg/l, 48 h, Leuciscus idus (Golden orfe)

Toxicity to daphnia and other aquatic invertebrates

Glutaral	:	EC50: 5,75 mg/l, 48 h, Daphnia magna (Water flea)
Ethanol	:	EC50: > 5.000 mg/l, 48 h, Daphnia magna (Water flea)

Toxicity to algae

Glutaral	:	EC50: 0,6 mg/l, 72 h, Desmodesmus subspicatus (green algae), OECD Test Guideline 201
Ethanol	:	IC50: > 100 mg/l, 72 h, Scenedesmus quadricauda (Green algae)

Toxicity to bacteria	:	EC50: 217 mg/l, OECD 209

Toxicity to fish (Chronic toxicity)

Glutaral	:	NOEC: 1,6 mg/l, 97 d, Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

Glutaral	:	NOEC: 2,5 mg/l, 21 d, Daphnia magna (Water flea)

12.2 Persistence and degradability

Biodegradability	:	Result: Readily biodegradable., OECD 301D / EEC 84/449 C6

Chemical Oxygen Demand (COD)	:	5.200 mg/l, Test substance: 1% solution

12.3 Bioaccumulative potential

Bioaccumulation

Glutaral	:	Bioaccumulation is unlikely.
Ethanol	:	Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	:	not applicable

12.4 Mobility in soil

Mobility

Glutaral	:	Mobile in soils
Ethanol	:	no data available

12.5 Results of PBT and vPvB assessment

Assessment	:	This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).

12.6 Other adverse effects

Additional ecological information	:	none

13. Disposal considerations

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	:	EWC 070601
Waste key for the unused product(Group)	:	Waste material of HZVA from fats, lubricants, soaps, detergents, disinfectants and personal protection products.

14. Transport information

ADR : UN number 1903

Proper shipping name
DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)

Transport hazard class 8

		Packaging group	III
		Environmental hazards	-
		Classification Code	C9
		ADR/RID-Labels	8
		ICAO-Labels	80
IMDG	:	UN number	1903

Proper shipping name
DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)

		Transport hazard class	8
		Packaging group	III
		Environmental hazards	-
		EmS	F-A, S-B
IATA	:	UN number	1903

Proper shipping name
DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)

Transport hazard class		8
Packaging group		III
Environmental hazards		-

Special precautions for user

ADR Tunnel restriction code: E

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Exempt

15. Regulatory information

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

Legislation on the control of major-accident hazards involving dangerous substances	:	Directive 96/82/EC does not apply
Volatile organic compounds (VOC) content	:	5 % Directive 1999/13/EC on the limitation of emissions of volatile organic compounds

15.2 Chemical Safety Assessment

Exempt

16. Other information

Full text of R-phrases referred to under sections 2 and 3

R11	Highly flammable.
R20/22	Harmful by inhalation and if swallowed.
R23/25	Toxic by inhalation and if swallowed.
R34	Causes burns.
R42/43	May cause sensitization by inhalation and skin contact.
R50	Very toxic to aquatic organisms.

Full text of H-Statements referred to under sections 2 and 3.

H225	Highly flammable liquid and vapour.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	Very toxic to aquatic life.

Further information

Changes compared with the previous edition!!!

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.

SECŢIUNEA 1: Identificarea substanţei/amestecului şi a societăţii/întreprinderii

1.1 Element de identificare a produsului

Denumirea comercială : thermosept® ED

1.2 Utilizări relevante identificate ale substanţei sau amestecului şi utilizări contraindicate

Utilizarea substanţei/amestecului : dezinfectanţi

Restricţii recomandate în timpul utilizării : Numai pentru utilizatori profesionişti.

1.3 Detalii privind furnizorul fişei cu date de securitate

Producător/Furnizor : Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt
Germany
Telefon: +4940521000
Fax: +494052100318
mail@schuelke.com
www.schuelke.com

Persoană de contact : Application Department HI
+49 (0)40/ 521 00 544
ADHI@schuelke.com

1.4 Număr de telefon care poate fi apelat în caz de urgenţă

Număr de telefon care poate fi apelat în caz de urgenţă : Institutul Naţional de Sănătate Publică, Bucuresti, str. Dr. Leonte, nr.1-3, sector 5
+40 21 318 36 06 apelabil intre orele 8.00-15.00

Număr de telefon care poate fi apelat în caz de urgenţă : +49 (0)40 / 52 100 –0

SECŢIUNEA 2: Identificarea pericolelor

2.1 Clasificarea substanţei sau a amestecului

Clasificare (REGULAMENTUL (CE) NR. 1272/2008)

Toxicitate acută, Categoria 4	H302: Nociv în caz de înghiţire.
Toxicitate acută, Categoria 4	H332: Nociv în caz de inhalare.
Corodarea pielii, Categoria 1B	H314: Provoacă arsuri grave ale pielii şi lezarea ochilor.
Sensibilizarea pielii, Categoria 1	H317: Poate provoca o reacţie alergică a pielii.
Sensibilizare respiratorie, Categoria 1	H334: Poate provoca simptome de alergie sau astm sau dificultăţi de respiraţie în caz de inhalare.
Toxicitate asupra unui organ ţintă specific - o singură expunere, Categoria 3	H335: Poate provoca iritarea căilor respiratorii.

Clasificare (67/548/CEE, 1999/45/CE)

Nociv	R20/22: Nociv prin inhalare şi prin înghiţire.
Coroziv	R34: Provoacă arsuri.
Nociv	R42/43: Poate provoca sensibilizare prin inhalare şi

în contact cu pielea.

2.2 Elemente pentru etichetă

Etichetare (REGULAMENTUL (CE) NR. 1272/2008)

Pictograme de pericol :

Cuvânt de avertizare : Pericol

Fraze de pericol :	H302 + H332	Nociv în caz de înghiţire sau inhalare
	H314	Provoacă arsuri grave ale pielii şi lezarea ochilor.
	H317	Poate provoca o reacţie alergică a pielii.
	H334	Poate provoca simptome de alergie sau astm sau dificultăţi de respiraţie în caz de inhalare.
	H335	Poate provoca iritarea căilor respiratorii.
Fraze de precauţie :	P261	Evitaţi să inspiraţi vaporii.
	P271	A se utiliza numai în aer liber sau în spaţii bine ventilate.
	P280	Purtaţi mănuşi de protecţie/ echipament de protecţie a ochilor/ echipament de protecţie a feţei.
	P301+P330+P331	ÎN CAZ DE ÎNGHIŢIRE: clătiţi gura. NU provocaţi voma.
	P303+P361+P353	ÎN CAZ DE CONTACT CU PIELEA (sau părul): scoateţi imediat toată îmbrăcămintea contaminată. Clătiţi pielea cu apă/ faceţi duş.
	P304+P340	ÎN CAZ DE INHALARE: transportaţi victima la aer liber şi menţineţi-o în stare de repaus, într-o poziţie confortabilă pentru respiraţie.
	P305+P351+P338+P310	ÎN CAZ DE CONTACT CU OCHII: clătiţi cu atenţie cu apă timp de mai multe minute. Scoateţi lentilele de contact, dacă este cazul şi dacă acest lucru se poate face cu uşurinţă. Continuaţi să clătiţi. Sunaţi imediat la un CENTRU DE INFORMARE TOXICOLOGICĂ sau un medic.

Componente potenţial periculoase ce trebuie să fie specificate pe etichetă:
111-30-8 Glutaral

2.3 Alte pericole

Acest amestec nu conţine nicio substanţă considerată ca fiind persistentă, bioacumulatoare sau toxică (PBT).
Nu sunt cunoscute riscuri speciale

SECŢIUNEA 3: Compoziţie/informaţii privind componenţii

3.2 Amestecuri

Natură chimică : Soluţia substanţelor următoare cu aditivi inofensivi.

Componente potenţial periculoase

Denumire chimică	Index-Număr Nr. CAS Nr.CE Număr de înregistrare	Clasificare (67/548/CEE)	Clasificare (REGULAMENTUL (CE) NR. 1272/2008)	Concentraţie (%)
Glutaral	605-022-00-X 111-30-8 203-856-5 01-2119455549-26-XXXX	T; R23/25 C; R34 Xn; R42/43 N; R50	Met. Corr. 1; H290 Acute Tox. 3; H301 Acute Tox. 3; H331 Skin Corr. 1B; H314 Resp. Sens. 1; H334 Skin Sens. 1; H317 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	20 %
Etanol	603-002-00-5 64-17-5 200-578-6 01-2119457610-43-XXXX	F; R11	Flam. Liq. 2; H225 Eye Irrit. 2; H319	5 - 15 %

Pentru explicaţii referitoare la abrevieri se va vedea secţiunea 16.

SECŢIUNEA 4: Măsuri de prim ajutor

4.1 Descrierea măsurilor de prim ajutor

Indicaţii generale : Se vor scoate imediat toate hainele contaminate.

Dacă se inhalează : Se va transporta victima la aer proaspăt şi se va menţine în stare de repaus. Nu se va face respiraţie artificială gură-la-gură sau gură-la-nas. Se vor folosi aparate/ instrumente speciale. Dacă simptomele persistă se va chema un medic.

În caz de contact cu pielea : Se va spăla imediat cu multă apă timp de cel puţin 15 minute. Dacă simptomele persistă se va chema un medic.

În caz de contact cu ochii : În caz de contact cu ochii se vor scoate lentilele de contct şi se va clăti imediat cu multă apă, inclusiv sub pleoape, cel puţin 15 minute. Se va chema un medic.

Dacă este ingerat : NU se va induce stare de vomă. Se va clăti gura cu apă. Se va da să bea mici cantităţi de apă. Se va chema un medic.

4.2 Cele mai importante simptome şi efecte, atât acute, cât şi întârziate

Simptome : Se va trata simptomatologic.

4.3 Indicaţii privind orice fel de asistenţă medicală imediată şi tratamentele speciale necesare

Tratament	:	Pentru sfaturi de specialitate medicii trebuie să se adreseze Serviciului de informaţii referitoare la otrăvuri.

SECŢIUNEA 5: Măsuri de combatere a incendiilor

5.1 Mijloace de stingere a incendiilor

Mijloace de stingere corespunzătoare	:	Pulbere uscată, Spumă, Jet de apă, Bioxid de carbon (CO2)
Mijloace de stingere necorespunzătoare	:	Jet de apă puternic

5.2 Pericole speciale cauzate de substanţa sau amestecul în cauză

Riscuri specifice în timpul luptei împotriva incendiilor	:	Nu există informaţii disponibile.
Risc specific corespunzător substanţei sau produsului însuşi, produselor acestuia de ardere sau gazelor degajate	:	În caz de incendiu se poate degaja:, Monoxid de carbon, Bioxid de carbon (CO2)

5.3 Recomandări destinate pompierilor

echipamentelor speciale de protecţie pentru pompieri	:	În cazul unui incendiu, se va purta un aparat respirator autonom.

SECŢIUNEA 6: Măsuri de luat în caz de dispersie accidentală

6.1 Precauţii personale, echipament de protecţie şi proceduri de urgenţă

Măsurile de precauţie pentru protecţia personală	:	Se va asigura ventilaţie adecvată. Se va folosi echipament de protecţie individual.

6.2 Precauţii pentru mediul înconjurător

Precauţii pentru mediul înconjurător	:	Nu se va deversa în apele de suprafaţă.

6.3 Metode şi material pentru izolarea incendiilor şi pentru curăţenie

Metodele de curăţare	:	Se va şterge cu un material absorbant (spre exemplu stofă, lână). Se va absorbi cu un material absorbant inert (spre exemplu nisip, silicagel, liant pentru acizi, liant universal, rumeguş).

6.4 Trimiteri către alte secţiuni

Se va consulta Secţiunea 8 + 13

SECŢIUNEA 7: Manipularea şi depozitarea

7.1 Precauţii pentru manipularea în condiţii de securitate

Sfaturi de manipulare în condiţii de securitate	:	Se va evita depăşirea limitelor de expunere profesională (a se vedea capitolul 8). Se va folosi numai cu o ventilaţie adecvată/protecţie personală adecvată.
Măsuri de protecţie împotriva incendiului şi a exploziei	:	Nu sunt necesare măsuri speciale de luptă împotriva incendiilor.
Măsuri de igienă	:	Se vor scoate imediat toate hainele contaminate.

7.2 Condiţii de depozitare în condiţii de securitate, inclusiv eventuale incompatibilităţi

Cerinţe pentru spaţiile de depozitare şi containere	:	Se va păstra la temperatura camerei, în recipienţi de original.
Informaţii suplimentare asupra condiţiilor de depozitare	:	Se va ţine ferit de lumina directă a soarelui. Se va păstra departe de căldură. A se păstra ambalajul închis ermetic.
Măsuri de protecţie în cazul depozitării în locuri comune	:	Se va păstra separat faţă de mâncare şi băutură.

7.3 Utilizare finală specifică (utilizări finale specifice)

Utilizare (utilizări) specifică (specifice)	:	nici unul

SECŢIUNEA 8: Controale ale expunerii/protecţia personală

8.1 Parametri de control

Concentrație maximă de lucru

Componente	Nr. CAS	Tipul valorii (Formă de expunere)	Parametri de control	Bază
Glutaral	111-30-8	TLV	0,05 ppm	ACGIH
Etanol	64-17-5	Valoare limită acceptabilă	500 ppm 960 mg/m3	TRGS 900
Etanol	64-17-5	Valoare limită de expunere ce nu trebuie depăşită în timpul oricărei perioade de lucru	1.000 ppm 1.920 mg/m3	TRGS 900
Etanol	64-17-5	Valoare limită acceptabilă	1.000 ppm 1.900 mg/m3	OSHA

Nivel la care nu apar efecte (DNEL) în conformitate cu Reglementările UE No. 1907/2006:

Glutaral	:	Utilizare finale: Lucrători, Căi de expunere: Inhalare, Efecte potenţiale asupra sănătăţii: Efecte locale pe termen lung, Valoare: 0,25 mg/m3
Etanol	:	Utilizare finale: Lucrători, Căi de expunere: Inhalare, Efecte potenţiale asupra sănătăţii: Efecte acute, Efecte locale, Valoare: 1900 mg/m3 Utilizare finale: Lucrători, Căi de expunere: Contact cu pielea, Efecte potenţiale asupra sănătăţii: Efecte cronice, Valoare: 343 mg/m3 Utilizare finale: Lucrători, Căi de expunere: Inhalare, Efecte potenţiale asupra sănătăţii: Efecte cronice, Valoare: 950 mg/m3

Concentraţie predictibilă fără efect (PNEC) în conformitate cu Reglementările UE No. 1907/2006:

Glutaral	:	Apă proaspătă, Valoare: 0,0025 mg/l Apă de mare, Valoare: 0,00025 mg/l Sediment de apă curgătoare, Valoare: 5,27 mg/kg Sediment marin, Valoare: 0,527 mg/kg Sol, Valoare: 0,03 mg/kg Efecte pe staţia de tratare a apa uzată, Valoare: 0,8 mg/l Procesare intermitentă/eliberare, Valoare: 0,006 mg/l
Etanol	:	Apă proaspătă, Valoare: 0,96 mg/l Apă de mare, Valoare: 0,79 mg/l Sediment de apă curgătoare, Valoare: 3,6 mg/kg Sol, Valoare: 0,63 mg/kg

8.2 Controale ale expunerii

Echipamentul individual de protecţie

Protecţia ochilor	:	Ochelari de protecţie prevăzuţi cu apărători laterale, în conformitate cu EN 166
Protecţia mâinilor	:	Protecţie contra contra improşcărilor: Mănuşi de cauciuc nitril de unică folosinţă, spre exemplu Dermatril (Grosimea stratului: 0,11 mm) fabricate de către KCL sau alte mănuşi ce asigură aceiaşi protecţie. Contact prelungit: Mănuşi de cauciuc nitril, spre exemplu. Camatril (>480 min., Grosimea stratului: 0,40 mm) sau mănuşi de cauciuc butil, spre exemplu. Butoject (>480 min., Grosimea stratului: 0,70 mm) fabricat de către KCL sau alte mănuşi ce asigură aceeaşi protecţie.
Protecţia respiraţiei	:	NU este necesar, cu excepţia cazului în care se formează aerosoli.
Măsuri de protecţie	:	Evitaţi contactul cu pielea şi ochii. A nu inspira vaporii.

Controlul expunerii mediului

Indicaţii generale	:	Nu se va deversa în apele de suprafaţă.

SECŢIUNEA 9: Proprietăţile fizice şi chimice

9.1 Informaţii privind proprietăţile fizice şi chimice de bază

Aspect	:	lichid
Culoare	:	incolor
Miros	:	înţepător(oare)
Pragul de acceptare a mirosului	:	nedeterminat
Punctul de aprindere	:	63 °C, DIN 51755 Part 1
Temperatură de aprindere	:	Etanol: > 360 °C
Temperatura de autoaprindere	:	nedeterminat
Limită inferioară de explozie	:	Etanol: 3,1 %(V)
Limită superioară de explozie	:	Etanol: 15 %(V)
Inflamabilitate	:	Nu menţine arderea.
Proprietăţi explozive	:	Nu există date

Proprietăţi oxidante	:	Nu există date
pH	:	circa 3,6, 20 °C, concentrat
Punctul de topire/punctul de îngheţare	:	< -5 °C
Temperatura de descompunere		Nu există date
Temperatură de fierbere/interval de temperatură de fierbere	:	circa 90 °C,
Presiunea de vapori	:	circa 35 hPa, 20 °C,
Densitatea de vapori relativă	:	Nu există date
Densitate	:	circa 1,04 g/cm3, 20 °C
Solubilitate în apă:	:	în toate proporţiile, 20 °C
Coeficientul de partiţie: n-octanol/apă	:	Nu se aplică
Vâscozitate dinamică	:	circa 3,2 mPa*s, 20 °C, DIN 53019,
Viteza de evaporare	:	Nu există date

9.2 Alte informaţii

Nu există date

SECŢIUNEA 10: Stabilitate şi reactivitate

10.1 Reactivitate

Nu se conoaşte nici o reacţie periculoasă în condiţii normale de folosire.

10.2 Stabilitate chimică

Produsul este stabil chimic.

10.3 Posibilitatea de reacţii periculoase

Nimic previzibil în mod normal.

10.4 Condiţii de evitat

Se va feri de îngheţ, căldură şi lumina soarelui.

10.5 Materiale incompatibile

Baze tari, Acizi tari şi agenţi oxidanţi, Amine, Amoniac

10.6 Produşi de descompunere periculoşi

Nimic previzibil în mod normal.

SECŢIUNEA 11: Informaţii toxicologice

11.1 Informaţii privind efectele toxicologice

Toxicitate acută

Produs

Toxicitate acută orală	:	Estimarea toxicităţii acute: 497 mg/kg, Estimarea toxicităţii orale acute în conformitate cu metoda de calcul prezentată în GHS (Sistemul de harmonizare global, Partea 3, capitolul 3.1)., Nociv în caz de înghiţire.
Toxicitate acută prin inhalare	:	Estimarea toxicităţii acute: 2,5 mg/l, în conformitate cu metoda

		de calcul prezentată în GHS (Sistemul de harmonizare global, Partea 3, capitolul 3.1)., Nociv în caz de inhalare.
Toxicitate acută dermică	:	Estimarea toxicităţii acute: > 5000 mg/kg, în conformitate cu metoda de calcul prezentată în GHS (Sistemul de harmonizare global, Partea 3, capitolul 3.1).

Corodarea/iritarea pielii

Produs

Provoacă arsuri grave ale pielii şi lezarea ochilor., Metoda de calculare

Lezarea gravă/iritarea ochilor

Produs

Provoacă arsuri grave ale pielii şi lezarea ochilor., Metoda de calculare

Sensibilizarea căilor respiratorii sau a pielii

Produs

Poate provoca o reacţie alergică a pielii.
Poate provoca simptome de alergie sau astm sau dificultăţi de respiraţie în caz de inhalare.

Mutagenitatea celulelor germinative

Componente:

Glutaral:

Genotoxicitate in vitro	:	Rezultate contradictorii au fost obţinute în diferite studii.
Mutagenitatea celulelor germinative- Evaluare	:	Nu a prezerntat efecte mutagene în decursul experimentelor pe animale.

Etanol:

Genotoxicitate in vitro	:	Nu este mutagen conform testului Ames. Ghid de testare OECD 471
Genotoxicitate in vivo	:	nemutagen
Mutagenitatea celulelor germinative- Evaluare	:	Testele pe culturi bacteriene sau de celule de mamifere nu au evidenţiat efecte mutagene.

Cancerogenitatea

Componente:

Glutaral:

Cancerogenitatea - Evaluare	:	Testele pe animale nu au arătat nici un fel de efecte cancerigene.

Etanol:

Cancerogenitatea - Evaluare	:	Nu a prezentat efecte cancerigene în decursul experimentelor pe animale.

Toxicitatea pentru reproducere

Componente:

Glutaral:

Toxicitatea pentru reproducere - Evaluare	:	Testele pe animale nu au arătat nici un fel de efecte referitoare la fertilitate.
Toxicitate teratogenă - Evaluare	:	Nu a prezentat efecte teratogene în decursul experimentelor pe animale.

Etanol:

Efecte asupra dezvoltării fătului	:	Şobolan, Oral(ă), NOAEL: 2.000 mg/kg
Toxicitatea pentru reproduce-	:	În cadrul testelor pe animale a apărut un risc de alterare a

re - Evaluare | fertilităţii numai după administrarea de doze foarte mari din acestă substanţă.

Toxicitate teratogenă - Evaluare : Experimentele pe animale au evidenţiat efecte mutagene şi teratogene.

STOT (toxicitate asupra organelor ţintă specifice) - expunere unică

Produs

Poate provoca iritarea căilor respiratorii.

STOT (toxicitate asupra organelor ţintă specifice) - expunere repetată

Componente:

Glutaral:
Nu există date

Toxicitate la doză repetată

Componente:

Glutaral:
Nu au fost observate efecte adverse la testele de toxicitate critică.
Etanol:
Şobolan: NOAEL: 2.400 mg/kg, Oral(ă)

Toxicitate referitoare la aspiraţie
Nu există date

Informaţii suplimentare

Produs

Nu există informaţii disponibile pentru produsul însuşi.

SECŢIUNEA 12: Informaţii ecologice

12.1 Toxicitate

Produs

Toxicitate pentru bacterii : EC50: 217 mg/l, OECD 209

12.2 Persistenţă şi degradabilitate

Produs

Biodegradare : Uşor biodagradabil. OCDE 301D / CEE 84/449 C6
Necesităţi în oxigen de natură chimică (NOC) : 5.200 mg/l, soluţie 1%

Componente:

Glutaral:
Biodegradare : Uşor biodagradabil. 90 - 100 o/o, 28 d, Îndrumar de test OECD 301 A

Etanol:
Biodegradare : Uşor biodagradabil.

12.3 Potenţial de bioacumulare

Produs

Coeficientul de partiţie: n-octanol/apă : Nu se aplică

Componente:

Glutaral:

Biocumulare	:	Nu se bioacumulează.
Coeficientul de partiţie: n-octanol/apă	:	log Pow: circa -0,36 (23 °C) , pH: 7, Directiva 92/69/CEE, A.8

Etanol:

Biocumulare	:	Bioacumularea este improbabilă.
Coeficientul de partiţie: n-octanol/apă	:	log Pow: -0,14, calculat

12.4 Mobilitate în sol

Componente:

Glutaral:

Mobilitate	:	Mobil în diverse tipuri de sol

Etanol:

Mobilitate	:	Nu există date

12.5 Rezultatele evaluării PBT şi vPvB

Produs
Acest amestec nu conţine nicio substanţă considerată ca fiind persistentă, bioacumulatoare sau toxică (PBT).

12.6 Alte efecte adverse

Produs

Informaţii ecologice adiţionale	:	nici unul

SECŢIUNEA 13: Consideraţii privind eliminarea

13.1 Metode de tratare a deşeurilor

Produs	:	Se va elimina produsul conform cu numărul european de eliminare a deşeurilor (Codul European al Deşeurilor).
Ambalaje contaminate	:	Se vor da ambalajele goale unei intreprinderi de reciclare.
Codul de deşeu pentru produsul nefolosit	:	CED 070601
Codul de deşeu pentru produsul nefolosit(Grup)	:	Deşeuri rezultate în urma producerii, preparării, vânzării şi utilizării de grăsimi, lubrifianţi, săpunuri, detergenţi, desinfectanţi şi produşi pentru protecţie personală.

SECŢIUNEA 14: Informaţii referitoare la transport

14.1 Numărul ONU

ADR	:	UN 1903
IMDG	:	UN 1903
IATA	:	UN 1903

14.2 Denumirea corectă ONU pentru expediţie

ADR	:	DEZINFECTANT, LICHID, COROZIV, N.O.S. (Glutaral)

IMDG	:	DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)
IATA	:	Disinfectant, liquid, corrosive, n.o.s. (Glutaral)

14.3 Clasa (clasele) de pericol pentru transport

ADR	:	8
IMDG	:	8
IATA	:	8

14.4 Grupul de ambalare

ADR

Grupul de ambalare	:	III
Cod de clasificare	:	C9
Nr.de identificare a pericolului	:	80
Etichete	:	8
Cod de restricţionare în tuneluri	:	E

IMDG

Grupul de ambalare	:	III
Etichete	:	8
EmS Cod	:	F-A, S-B

IATA

Instrucţiuni de ambalare (avioane cargo)	:	856
Grupul de ambalare	:	III
Etichete	:	8

14.5 Pericole pentru mediul înconjurător

ADR

Periculos pentru mediul înconjurător	:	nu

IMDG

Poluanţii marini	:	nu

14.6 Precauţii speciale pentru utilizatori

Pentru protecţia individuală a se vedea paragraful 8.

14.7 Transport în vrac, în conformitate cu anexa II la MARPOL 73/78 şi Codul IBC

Nu se aplică pentru produse precum cel furnizat.

SECŢIUNEA 15: Informaţii de reglementare

15.1 Regulamente/legislaţie în domeniul securităţii, sănătăţii şi al mediului specifice (specifică) pentru substanţa sau amestecul în cauză

Legislaţie referitoare la controlul riscurilor de accident majore implicând substanţe	:	Nu se aplică Directiva 96/82/CE

periculoase

Compuşi organici volatili	:	5 %, Directiva 2010/75/CE referitoare la limitarea emisiilor de compuşi organici volatili

15.2 Evaluarea securităţii chimice

Exceptat

SECŢIUNEA 16: Alte informaţii

Text complet al frazelor R

R11	:	Foarte inflamabil.
R23/25	:	Toxic prin inhalare şi prin înghiţire.
R34	:	Provoacă arsuri.
R42/43	:	Poate provoca sensibilizare prin inhalare şi în contact cu pielea.
R50	:	Foarte toxic pentru organismele acvatice.

Text complet al declaraţiilor H

H225	:	Lichid şi vapori foarte inflamabili.
H290	:	Poate fi corosiv pentru metale.
H301	:	Toxic în caz de înghiţire.
H314	:	Provoacă arsuri grave ale pielii şi lezarea ochilor.
H317	:	Poate provoca o reacţie alergică a pielii.
H319	:	Provoacă o iritare gravă a ochilor.
H331	:	Toxic în caz de inhalare.
H334	:	Poate provoca simptome de alergie sau astm sau dificultăţi de respiraţie în caz de inhalare.
H335	:	Poate provoca iritarea căilor respiratorii.
H400	:	Foarte toxic pentru mediul acvatic.
H411	:	Toxic pentru mediul acvatic cu efecte pe termen lung.

Text complet al altor abrevieri

Acute Tox.	Toxicitate acută
Aquatic Acute	Toxicitatea acută pentru mediul acvatic
Aquatic Chronic	Toxicitatea cronică pentru mediul acvatic
Eye Irrit.	Iritarea ochilor
Flam. Liq.	Lichide inflamabile
Met. Corr.	Corosive pentru metale
Resp. Sens.	Sensibilizare respiratorie
Skin Corr.	Corodarea pielii
Skin Sens.	Sensibilizarea pielii
STOT SE	Toxicitate asupra unui organ ţintă specific - o singură expunere

Informaţii suplimentare

Modificările faţă de ediţia precedentă sunt marcate pe margine.

Informaţiile conţinute în această fişă tehnică de securitate au fost stabilite pe baza conoştiinţelor, informaţiilor şi presupunerilor noastre la data publicării acestui document.

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 substance 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 safety 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

E-mail address of person responsible for the SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ApplicationDepartment.SM@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements	:	H315 Causes skin irritation. H319 Causes serious eye irritation.
Supplemental Hazard Statements	:	EUH208 Contains Subtilisin. May produce an allergic reaction.
Precautionary statements	:	P280 Wear protective gloves/ eye protection. 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.
Special labelling of certain mixtures	:	Labelling according to Regulation (EC) No. 648/2004: (5 - 15 % anionic surfactants, < 5 % non-ionic surfactants, < 5% Polycarboxylates, enzymes)

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.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Sodium cumenesulfonate	15763-76-5 239-854-6 - - - 01-2119489411-37-XXXX	Eye Irrit. 2; H319	5 - 15
2-aminoethanol	141-43-5 205-483-3 603-030-00-8 01-2119486455-28-XXXX	Acute Tox. 4; H302 Acute Tox. 4; H312 Acute Tox. 4; H332 Skin Corr. 1B; H314 STOT SE 3; H335 Aquatic Chronic 3; H412	< 5
Sodim-etasulfate	126-92-1 204-812-8 - - - 01-2119971586-23-XXXX	Skin Irrit. 2; H315 Eye Dam. 1; H318	< 5

Alkylpolyethylen-glycol-polybutylen-glycolether	120313-48-6 Polymer - - - - - -	Aquatic Acute 1; H400; M = 1 Aquatic Chronic 3; H412	< 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	< 1
Alcohols, C13-15-branched and linear, butoxylated ethoxylated	111905-53-4 Polymer - - - - - -	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 3; H412	< 1

Non-hazardous ingredients

Chemical name	Index-Number CAS-No. EC-No.	Concentration (% w/w)
Glycerol	- - - 56-81-5 200-289-5	< 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 : Move to fresh air.
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 : In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
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 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 a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : Carbon dioxide (CO2)
Carbon monoxide
Nitrogen oxides (NOx)

5.3 Advice for firefighters

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

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. Never mix concentrates directly.
Advice on protection against fire and explosion	:	No special protective measures against fire required. The product itself does not burn.
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 storage 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

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium cumenesulfonate	Workers	Skin contact	Long-term systemic effects	136,25 mg/kg
	Workers	Skin contact	Long-term local effects	0,096 mg/cm2
	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 effects	3,3 mg/m3
Sodim-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 effects	0,06 mg/m3

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

Substance name	Environmental Compartment	Value
Sodium cumenesulfonate	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	0,025 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
Sodim-etasulfate	Fresh water	0,1357 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	0,06 mg/l
	Marine water	0,006 mg/l
	Effects on waste water treatment plants	65000 mg/l

8.2 Exposure controls

Personal protective equipment

Eye 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.

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	:	yellow
Odour	:	characteristic
Odour Threshold	:	not determined
pH	:	ca. 11 (20 °C)
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)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Vapour density	:	No data available
Relative density	:	ca. 1,10 g/cm3 (20 °C, 1.013 hPa)
Solubility(ies)		
Water solubility	:	in all proportions (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
Explosive properties	:	No data available
Oxidizing properties	:	No data available

9.2 Other information

Flammability (liquids) : Does not sustain combustion.

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

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 25 mg/l

Acute dermal toxicity : Acute toxicity estimate: > 5.000 mg/kg

Components:

Sodium cumenesulfonate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l

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.

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

Sodim-etasulfate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Alkylpolyethylen-glycol-polybutylen-glycolether:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: Calculated value

Acute inhalation toxicity : Remarks: not determined

Acute dermal toxicity : Remarks: not determined

Subtilisin:

Acute oral toxicity : LD50: 1.800 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

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

Acute oral toxicity : LD50 (Rat): > 300 - < 2.000 mg/kg
Assessment: Harmful if swallowed.

Acute inhalation toxicity : Remarks: not determined

Acute dermal toxicity : Remarks: not determined

Skin corrosion/irritation

Product:

Assessment : Causes skin irritation.
Method : Calculation method

Components:

Sodium cumenesulfonate:

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

Sodim-etasulfate:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	Causes skin irritation.

Alkylpolyethylen-glycol-polybutylen-glycolether:

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

Subtilisin:

Method	:	OECD Test Guideline 404
Result	:	Causes skin irritation.

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

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	irritating

Serious eye damage/eye irritation

Product:

Assessment	:	Causes serious eye irritation.
Method	:	Calculation method

Components:

Sodium cumenesulfonate:

Species	:	Rabbit
Assessment	:	Causes serious eye irritation.
Method	:	OECD Test Guideline 405

2-aminoethanol:

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

Sodim-etasulfate:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	Causes serious eye damage.

Alkylpolyethylen-glycol-polybutylen-glycolether:

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

Subtilisin:

Method	:	OECD Test Guideline 405
Result	:	Causes serious eye damage.

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

Species	:	Rabbit
Assessment	:	Causes serious eye irritation.
Method	:	OECD Test Guideline 405

Respiratory or skin sensitisation

Components:

Sodium cumenesulfonate:

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

Sodim-etasulfate:

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

Alkylpolyethylen-glycol-polybutylen-glycolether:

Remarks	:	No data available

Subtilisin:

Result	:	Does not cause respiratory sensitisation.
Remarks	:	largely based on human evidence

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

Remarks : No data available

Germ cell mutagenicity

Components:

Sodium cumenesulfonate:

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
Remarks: Non mutagenic

Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

2-aminoethanol:

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

Sodim-etasulfate:

Germ cell mutagenicity- Assessment : No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

Genotoxicity in vitro : Remarks: Not classified due to data which are conclusive although insufficient for classification.

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

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

Germ cell mutagenicity- Assessment : No data available

Carcinogenicity

Components:

Sodium cumenesulfonate:

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

2-aminoethanol:

Carcinogenicity - Assessment : Not classifiable as a human carcinogen.

Sodim-etasulfate:

Carcinogenicity - Assessment : No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

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

Subtilisin:

Carcinogenicity - Assessment : No data available

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

Carcinogenicity - Assessment : No data available

Reproductive toxicity

Components:

Sodium cumenesulfonate:

Effects on foetal development : Species: Rat
Application Route: Oral
General Toxicity Maternal: NOAEL: 3.000 mg/kg body weight
Developmental Toxicity: NOAEL F1: 3.000 mg/kg body weight

Reproductive toxicity - Assessment : study scientifically unjustified

2-aminoethanol:

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

Sodim-etasulfate:

Reproductive toxicity - Assessment : No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

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

Subtilisin:

Reproductive toxicity - Assessment : No data available

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

Reproductive toxicity - Assessment : No data available

STOT - single exposure

Components:

Sodium cumenesulfonate:

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

2-aminoethanol:

Assessment : May cause respiratory irritation.

Sodim-etasulfate:

Remarks : No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

Remarks : No data available

Subtilisin:

Assessment : May cause respiratory irritation.

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

Remarks : No data available

STOT - repeated exposure

Components:

Sodium cumenesulfonate:

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.

Sodim-etasulfate:

Remarks : No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

Remarks : No data available

Subtilisin:

Remarks : No data available

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

Remarks : No data available

Repeated dose toxicity

Components:

Sodium cumenesulfonate:

Species	:	Mouse
NOAEL	:	440 mg/kg
LOAEL	:	1.300 mg/kg
Application Route	:	Dermal
Method	:	OECD Test Guideline 411
Target Organs	:	Skin
Remarks	:	Subchronic toxicity

Aspiration toxicity

Components:

Alkylpolyethylen-glycol-polybutylen-glycolether:

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

Further information

Product:

Remarks : The product has not been tested.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Sodium cumenesulfonate:

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	:	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 other aquatic invertebrates	:	EC50 (Daphnia magna): 65 mg/l Exposure time: 48 h Method: EG 84/449
Toxicity to algae	:	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)	:	0,85 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Sodim-etasulfate:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia (water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h

Alkylpolyethylen-glycol-polybutylen-glycolether:

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
Toxicity to algae	:	EC50 (algae): 0,1 - 1 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to daphnia and other	:	NOEC: > 0,1 - < 1 mg/l

aquatic invertebrates (Chronic toxicity)		Exposure time: 21 d Species: Daphnia magna (Water flea)

Subtilisin:

Toxicity to fish	:	LC50 (Fish): 0,1 - 1 mg/l Exposure time: 96 h
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	:	ErC50 (algae): 0,83 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	1

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

Toxicity to fish	:	LC50 (Leuciscus idus): 1 - 10 mg/l Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 : 0,1 - 1 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 : 0,1 - 1 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	:	Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0,1 - 1 mg/l

12.2 Persistence and degradability

Product:

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

Components:

Sodium cumenesulfonate:

Biodegradability	:	Result: Readily biodegradable.

2-aminoethanol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: > 90 % Exposure time: 21 d

Method: OECD Test Guideline 301A

Sodim-etasulfate:

Biodegradability : Result: Readily biodegradable, according to appropriate OECD test.
Biodegradation: > 60 %
Exposure time: 14 d
Method: OECD 301D / EEC 84/449 C6

Alkylpolyethylen-glycol-polybutylen-glycolether:

Biodegradability : Result: Readily biodegradable, according to appropriate OECD test.

Subtilisin:

Biodegradability : Remarks: No data available

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

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD 301B/ ISO 9439/ EEC 84/449 C5

12.3 Bioaccumulative potential

Components:

Sodium cumenesulfonate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

2-aminoethanol:

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

Sodim-etasulfate:

Bioaccumulation : Remarks: No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

Bioaccumulation : Remarks: Accumulation in aquatic organisms is unlikely.

Subtilisin:

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : Remarks: No data available

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

Bioaccumulation : Remarks: Does not significantly accumulate in organisms.

12.4 Mobility in soil

Components:

Sodium cumenesulfonate:

Mobility : Remarks: Not expected to adsorb on soil.

2-aminoethanol:

Mobility : Remarks: Not expected to adsorb on soil.

Sodim-etasulfate:

Mobility : Remarks: No data available

Alkylpolyethylen-glycol-polybutylen-glycolether:

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

Subtilisin:

Mobility : Remarks: Not applicable

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

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

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..

12.6 Other adverse effects

Product:

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

SECTION 13: Disposal considerations

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, detergents, 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

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants	:	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	:	none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

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 limit values.

15.2 Chemical safety assessment

Exempt

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.
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

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 concentra-

tion; 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; 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 and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

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.

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.