



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

schülke -t-

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectant for medical devices, wound care products and gel as listed in annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	004567 MR2
Certificate unique ID	170773612
Effective date	2021-02-01
Expiry date	2023-12-18
Frankfurt am Main	2021-02-01

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170773612
Effective date: 2021-02-01

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
acryl-des® Gebrauchslösung	IIa
acryl-des® Desinfektionstücher	IIa
antifect® AF (N)	IIa
antifect® N liquid	IIa
antifect® extra	IIa
aspirmatic®	IIa
boots wound healing gel	IIb
dentavon®	IIa
dentavon® liquid	IIa
gigasept® AF	IIb
gigasept® AF forte	IIb
gigasept® FF (neu)	IIb
gigasept® Instru AF	IIb
gigasept® med	IIb
gigasept® pearls	IIb
gigasonic®	IIb
gigazyme® Xtra	IIb
mikrozyd® AF liquid	IIa
mikrozyd® AF wipes	IIa
mikrozyd® alcohol free liquid	IIa
mikrozyd® alcohol free wipes jumbo	IIa
mikrozyd® liquid	IIa
mikrozyd® PAA wipes	IIb
mikrozyd® sensitive liquid	IIa
mikrozyd® sensitive wipes	IIa
mikrozyd® universal liquid	IIa
mikrozyd® universal wipes	IIa
mikrozyd® wipes	IIa
mucalgin®	IIa
mucapur® CD	IIa
mucocit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	IIa
octenisept® Gel	IIb
octenisept® wound gel	IIb



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Schülke & Mayr GmbH

Robert-Koch-Straße 2
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Device	Class
perform®	IIa
pursept® AF	IIa
pursept® A Xpress liquid	IIa
quartamon® med	IIa
rotasept®	IIb
septinol® SA	IIa
terralin® liquid	IIa
terralin® protect	IIa
thermosept® ED	IIb
thermosept® NDR	IIa
TPH® protect	IIa
SteraClar Daily	IIa
SteraDif Powder	IIa
SteraPex	IIb
SteraPex Rotary	IIb
SteraClens Alcohol Free	IIa
SteraClens	IIa
SteriWipe+ Alcohol Free	IIa
SteriWipe+	IIa
DESIMATIC-ID PLUS	IIb
DESIFOR-ONE multi wipes	IIa
DESIFOR-ONE PROTECT	IIa
B3	IIa
Pursept A Xpress S	IIa
ProCare Protect universal wipes	IIa
UnoDent Alcohol-free Wipes	IIa



CERTIFICATE



This is to certify that the company

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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 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	170774693
Effective date	2021-06-27
Expiry date	2024-06-26
Frankfurt am Main	2021-06-27



DQS Medizinprodukte GmbH

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Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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



Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170774693
Effective date: 2021-06-27

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 France S.A.R.L.

50 boulevard National
92250 La Garenne
France

Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Schülke & Mayr UK Ltd.

Cygnat 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.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

schülke 

THERMOSEPT ED

No Change Service!

Version 02.04

Revision Date 29.10.2012

Print Date 04.12.2013

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 Sub- : Disinfectants
stance/Mixture
Recommended restrictions : Restricted to professional users.
on use

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 num- : UK Poisons Emergency number: 0870 600 6266
ber
Emergency telephone num- : +49 (0)40 / 52 100 -0
ber

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

THERMOSEPT ED**No Change Service!**

Version 02.04

Revision Date 29.10.2012

Print Date 04.12.2013

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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.

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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

THERMOSEPT ED**No Change Service!**

Version 02.04

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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/m ³	TRGS 900
Ethanol	64-17-5	Ceiling Limit Value	1.000 ppm 1.920 mg/m ³	TRGS 900
Ethanol	64-17-5	Permissible exposure limit	1.000 ppm 1.900 mg/m ³	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)

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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/cm ³ , 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

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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

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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

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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

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



Proper shipping name

DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (Glutaral)

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

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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.

thermosept® NKZ *No Change Service!*Version
03.03Revision Date:
28.09.2017Date of last issue: 13.12.2016
Date of first issue: 07.09.2001**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : thermosept® NKZ

1.2 Relevant identified uses of the substance or mixture and uses advised againstUse of the Sub-
stance/Mixture : AdditiveRecommended 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.comE-mail address of person
responsible for the
SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ADHI@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)**1.4 Emergency telephone number**Emergency telephone num-
ber : 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)**Corrosive to metals, Category 1
Eye irritation, Category 2H290: May be corrosive to metals.
H319: Causes serious eye irritation.**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Warning

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according to Regulation (EC) No. 1907/2006

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thermosept® NKZ **No Change Service!**

Version
03.03

Revision Date:
28.09.2017

Date of last issue: 13.12.2016
Date of first issue: 07.09.2001

Hazard statements : H290 May be corrosive to metals.
H319 Causes serious eye irritation.

Precautionary statements : 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.

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.

No special risks known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

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

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Citric acid monohydrate	5949-29-1 201-069-1 --- ---	Eye Irrit. 2; H319	30 - 50

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : Take off all contaminated clothing immediately.

|| If inhaled : If breathed in, move person into fresh air.

In case of skin contact : Wash with water and soap as a precaution.
If symptoms persist, call a physician.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
If eye irritation persists, consult a specialist.

If swallowed : Do NOT induce vomiting.
Drink water as a precaution.
If symptoms persist, call a physician.

thermosept® NKZ *No Change Service!*Version
03.03Revision Date:
28.09.2017Date of last issue: 13.12.2016
Date of first issue: 07.09.2001**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
Foam
Water spray jet
Carbon dioxide (CO₂)

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**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 : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning upMethods 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

thermosept® NKZ *No Change Service!*Version
03.03Revision Date:
28.09.2017

Date of last issue: 13.12.2016

Date of first issue: 07.09.2001

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Advice on safe handling : Never mix concentrates directly.
- Advice on protection against fire and explosion : No special protective measures against fire required.
- 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 : Keep away from heat. Keep container tightly closed. Recommended storage temperature: 5 - 25°C
- Advice on common storage : No materials to be especially mentioned.

7.3 Specific end use(s)

- Specific use(s) : none

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

none

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

Substance name	Environmental Compartment	Value
Citric acid monohydrate	Fresh water	0,44 mg/l
	Marine water	0,044 mg/l
	Fresh water sediment	7,52 mg/kg
	Marine sediment	0,752 mg/kg
	Soil	29,2 mg/kg

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 EU Directive 89/686/EEC 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.

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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 : colourless

Odour : nearly odourless

Odour Threshold : not determined

pH : ca. 2 (20 °C)

Melting point/freezing point : ca. 0 °C

Decomposition temperature : Not applicable

Boiling point/boiling range : ca. 100 °C

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit : Not applicable

Lower explosion limit : Not applicable

Vapour pressure : ca. 25 hPa (20 °C)

Vapour density : No data available

Relative density : ca. 1,17 g/cm³ (20 °C)

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. 4 mPa*s
Method: ISO 3219

Explosive properties : No data available

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Does not cause skin sensitisation.OECD Test Guideline 406

Germ cell mutagenicity**Components:****Citric acid monohydrate:**

Germ cell mutagenicity- Assessment : Non mutagenic

Carcinogenicity**Components:****Citric acid monohydrate:**

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

Reproductive toxicity**Components:****Citric acid monohydrate:**Effects on fertility : Rat, Oral, NOAEL: 2.500 mg/kg
Reproductive toxicity - Assessment : No toxicity to reproduction**STOT - single exposure****Components:****Citric acid monohydrate:**

|| No data available

STOT - repeated exposure**Components:****Citric acid monohydrate:**

|| No data available

Repeated dose toxicity**Components:****Citric acid monohydrate:**

Rat, NOAEL: 1.200 mg/kg, Oral

Aspiration toxicity

No data available

Further information**Product:**

No data is available on the product itself.

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Date of first issue: 07.09.2001**SECTION 12: Ecological information****12.1 Toxicity****Components:****Citric acid monohydrate:**

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 440 - 760 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other : EC50 (Daphnia magna): 85 - 120 mg/l
aquatic invertebrates Exposure time: 72 h
- Toxicity to algae : IC5 (Scenedesmus quadricauda (Green algae)): 640 mg/l

12.2 Persistence and degradability**Product:**

- Biodegradability : Result: Readily biodegradable.
Method: OECD 301D / EEC 84/449 C6
- Chemical Oxygen Demand : 2.900 mg/l
(COD) Test substance: 1 % solution

Components:**Citric acid monohydrate:**

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

12.3 Bioaccumulative potential**Components:****Citric acid monohydrate:**

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

12.4 Mobility in soil**Components:****Citric acid monohydrate:**

- Mobility : Remarks: No data available

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

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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**

IMDG	:	UN 3265
IATA (Cargo)	:	UN 3265

14.2 UN proper shipping name

IMDG	:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Citric acid monohydrate)
IATA (Cargo)	:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Citric acid monohydrate)

14.3 Transport hazard class(es)

IMDG	:	8
IATA (Cargo)	:	8

14.4 Packing group

IMDG	:	
Packing group	:	III
Labels	:	8
EmS Code	:	F-A, S-B
IATA (Cargo)	:	
Packing instruction (cargo aircraft)	:	856
Packing group	:	III
Labels	:	Corrosive

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14.5 Environmental hazards

IMDG

Marine pollutant : no

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 : Remarks: none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

Other regulations:

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

H319 : Causes serious eye irritation.

Full text of other abbreviations

Eye Irrit. : Eye irritation

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 Regula-

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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.

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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 neededTreatment : 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 (NO_x)**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 upMethods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).**6.4 Reference to other sections**see Section 8 + 13

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- 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/cm ²
	Workers	Inhalation	Long-term systemic effects	26,9 mg/m ³
2-aminoethanol	Workers	Skin contact	Long-term systemic effects	1 mg/kg
	Workers	Inhalation	Long-term local effects	3,3 mg/m ³
Sodim-etasulfate	Workers	Skin contact	Long-term systemic effects	4060 mg/kg
	Workers	Inhalation	Long-term systemic effects	285 mg/m ³
Subtilisin	Workers	Skin contact	Acute local effects	2000 ppm
	Workers	Inhalation	Long-term local effects	0,06 mg/m ³

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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.

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SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	liquid
Colour	:	yellow
Odour	:	characteristic
Odour Threshold	:	not determined
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/cm ³ (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

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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

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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.

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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

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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 TestGenotoxicity 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

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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

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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-etatsulfate:

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.

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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 : EC50 (Daphnia magna (Water flea)): > 100 mg/l
aquatic invertebrates : Exposure time: 48 h

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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 : EC50 (Daphnia magna): 65 mg/l
aquatic invertebrates : 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 tox- : 1,2 mg/l
icity) : Exposure time: 30 d
Species: Oryzias latipes (Orange-red killifish)

Toxicity to daphnia and other : 0,85 mg/l
aquatic invertebrates (Chron- : Exposure time: 21 d
ic toxicity) : Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

Sodim-etatsulfate:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia (water flea)): > 100 mg/l
aquatic invertebrates : 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 : EC50 (Daphnia magna): 0,1 - 1 mg/l
aquatic invertebrates : Exposure time: 48 h

Toxicity to algae : EC50 (algae): 0,1 - 1 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic tox- : 1
icity)

Toxicity to daphnia and other : NOEC: > 0,1 - < 1 mg/l

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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

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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.

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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.

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according to Regulation (EC) No. 1907/2006

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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

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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-

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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.

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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



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/cm ³ / 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 I FA	1/drum(s)	on request
thermosept X-tra 5 I KA	1/Canister	on request
thermosept X-tra 10 I KA	1/Canister	on request
thermosept Xtra 20 I KA	1/Canister	on request
thermosept X-tra SOKA 5 I 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



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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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REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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Nr.	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
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

✓ Conține([Reprezentant], 'endo') И Conține([Producator], 'mayr') И ([NameMake] Равно...