according to Regulation (EC) No. 1907/2006



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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

be

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

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R-phrase(s)	: R20/22 R34 R42/43	Causes burns.	lation and if swallowed.
S-phrase(s)	: S23 S26		vapour. ct with eyes, rinse immedi- of water and seek medical
	S36/37	7/39 Wear suitable p and eye/face pro	rotective clothing, gloves otection.
	S45	In case of accide	ent or if you feel unwell, Ivice immediately (show the
	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 %

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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 imme-

diately 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

Specific risk from the substance or the product itself, its combustion products or

evolved gases

: In the event of fire, wear self-contained breathing apparatus.

: Fire may cause evolution of:, Carbon monoxide, Carbon diox-

ide (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

Further information on stor-

age conditions

: Store at room temperature in the original container.

: 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

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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/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 protec-

tion.

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/cm3, 20 °C
Water solubility : 20 °C, in all proportions

Partition coefficient: n- : not applicable

octanol/water

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

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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.

In animal testing, risk of impaired fertility was shown only after Ethanol

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 ef-

fects.

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 Prep-

arations 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 al-

gae), 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 persis-

tent, bioaccumulating nor toxic (PBT).

12.6 Other adverse effects

Additional ecological infor-

mation

: none

13. Disposal considerations

13.1 Waste treatment methods

Product : Dispose of the product according to the defined EWC (Euro-

pean 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, deter-

gents, 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

IATA

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> Packaging group Ш 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)

Transport hazard class 8 Packaging group Ш Environmental hazards

EmS F-A, S-B : UN number 1903



Proper shipping name

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

Transport hazard class Packaging group Ш Environmental hazards

Special precautions for user

ADR Tunnel restriction code: Ε

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 substanc: Directive 96/82/EC does not apply

Volatile organic compounds

: 5%

Directive 1999/13/EC on the limitation of emissions of volatile (VOC) content

organic compounds

15.2 Chemical Safety Assessment

Exempt

16. Other information

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

R50

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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.

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.

Very toxic to aquatic organisms.

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.