according to Regulation (EC) No 1907/2006



Trade name: TR-3

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

1.1 Product identifier

Trade name: TR-3

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

Relevant identified uses: Cleaning agent

Intended purpose: Liquid, alkaline cleaning concentrate, universally applicable

in automatic and semi-automatic dosing systems of cleaning and disinfection machines (washers/washer disinfectors) incl. ultrasonic devices for automatic reprocessing of medical devices (e.g. general and rotary

instruments) in clinics and practices.

Uses advised against: None at intended use.

Note: The product is intended for professional users.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: ALPRO MEDICAL GMBH

Mooswiesenstraße 9

D-78112 St. Georgen (Germany) Telephone: +49 7725 9392-0 Telefax: +49 7725 9392-91 E-mail: alpro@alpro-medical.de Internet: www.alpro-medical.com

E-mail address for the competent person

responsible for the safety data sheet: doku@alpro-medical.de

1.4. Emergency telephone number

In-house emergency telephone number: +49 7725 9392-0

Monday – Friday from 08:00 am to 04:30 pm (UTC+1); for chemical information and legal information on

hazardous substances only

Poison centre: +49 761 19240

Poisoning information centre, Freiburg, Germany

(24 h / 7 d), English is spoken

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification in accordance with Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure	
Eye Irrit. 2; H319	Calculation method	
Skin Irrit. 2; H315	Calculation method	

Full text of hazard classes as well as H-phrases: see under SECTION 16.3.

Classification in accordance with Directive 1999/45/EC

see SECTION 16.1.

2.2. Label elements

according to Regulation (EC) No 1907/2006



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Label elements in accordance with Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms:

Signal word: Warning

Hazard components

for labelling:

H-phrases: H315 Causes skin irritation.

H319 Causes serious eye irritation.

P-phrases: P280 Wear protective gloves/eye protection/face protection.

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.

Label elements in accordance with Directive 1999/45/EC

see SECTION 16.2.

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII.

No further hazards known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterisation: Mixture of substances listed below with non-hazardous additions in

aqueous solution.

Hazardous ingredients

Chemical name	Identification numbers	Classification	Classification	Weight %
		in accordance	in accordance with	
		with Directive	Regulation (EC)	
		67/548/EEC	No 1272/2008	
Quaternary ammo-	CAS No: 63449-41-2	Xn; R21/22	Acute Tox. 4; H312	≥ 1 - < 2,5
nium compounds,	EC No: 264-151-6	C; R34	Acute Tox. 4; H302	
benzyl-C8-18-	Index No: 612-140-00-5	N; R50	Skin Corr. 1B; H314	
alkyldimethyl,			Aquatic Acute 1; H400	
chlorides				
Alkyl polyether	CAS No: 53563-70-5	Xi; R38-41	Skin Irrit. 2; H315	≥ 1 - < 2,5
carboxylic acid	EC No: 611-013-1		Eye Dam. 1; H318	

Full text of code letters, hazard classes, R- and H-phrases: see SECTION 16.3.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: First aider: Pay attention to self-protection!

Following inhalation: Move affected person into fresh air and keep still and warm. In case of

continued complaints seek medical advice.

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Following skin contact: Wash skin immediately with plenty of water and soap. In case of skin

reactions, consult a physician.

Following eye contact: Flush eyes immediately with flowing water for 10 to 15 minutes holding

eyelids apart. Remove contact lenses, if present and easy to do. Consult an

ophthalmologist.

Following ingestion: Rinse mouth with water. Let drink plenty of water. Do not induce vomiting.

Consult a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Causes skin irritation. Causes serious eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water spray jet, alcohol resistant foam, extinguishing powder,

carbon dioxide (CO₂)

Unsuitable extinguishing media: Full water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon monoxide (CO₂), nitrogen oxides (NO_x)

5.3. Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus.

Further information: Cool endangered containers with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Use personal protective equipment. See SECTION 8.2.

Avoid skin and eye contact. Special danger of slipping by leaked/spilled product.

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. Environmental precautions

Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Containment

For large spills, dyke spilled material or otherwise contain material to ensure runoff does not reach a waterway. Cover or seal drains.

Cleaning up

Wipe up small amounts with absorbent material (e.g. cloth, fleece). Absorb large amounts with liquid-binding material (sand, diatomaceous earth, universal binder, sawdust). Collect in suitable, closed containers for disposal. Clean contaminated surfaces thoroughly.

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Other information

Inappropriate containment and cleaning methods are not known.

6.4. Reference to other sections

Information on safe handling see SECTION 7.1.
Information on personal protective equipment see SECTION 8.2.
Information on disposal see SECTION 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions

Avoid contact with skin and eyes. Fill refill packages only in labelled original bottles.

Advice on general occupational hygiene

When using do not eat, drink or smoke. Wash hands before breaks and at end of work. Keep away from food and drink.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels: Keep only in the original container. Keep container tightly

closed and kept upright to prevent any leakage.

Advice on common storage: Not necessary

Further information on storage conditions: Not necessary

Storage class ([DE] TRGS 510): LGK 12 Non-combustible liquids

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific end uses are stipulated.

Industry and sector specific guidance

[DE] TRGS 525 – Hazardous substances in medical care facilities (Section 7 Activities with disinfectants); Issue: September 2014;

Source: GMBI 2014 page 1294-1307 of 13.10.2014 [No 63]; www.baua.de

[DE] DGUV rules 107-002 (former BGR 206) - Disinfection works in health service

Issue: July 1999; Source: www.dguv.de/publikationen

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Does not contain substances above concentration limits fixing an occupational exposure limit.

Biological limit values

Does not contain substances above concentration limits fixing a biological limit value.

Information on monitoring procedures

BS EN 482:2012-04-30; Title: Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents;
British version of EN 482:2012

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BS EN 689:1996-04-15; Title: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; British version of EN 689:1995

BS EN 14042:2003-04-24; Title: Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents; British version of EN 14042:2003

8.2. Exposure controls

Appropriate engineering controls

Technical and organisational protective measures

The eyewash station (or eyewash bottle) must be located near the workplace.

Personal protective equipment

Eye/face protection: Safety glasses with side protection according to EN 166

Skin protection:

Hand protection: Protective gloves according to EN 374

Splash guard:

Disposable gloves made of nitrile rubber (thickness 0.11 mm)

Permanent contact (> 480 min):

Protective gloves made of nitrile rubber (thickness 0.40 mm)

Other skin protection: Not necessary when used as intended.

Respiratory protection: Not necessary when used as intended.

Thermal hazards: No special protective measures necessary.

Environmental exposure controls

Do not discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: clear, yellowish liquid

Odour: characteristic
Odour threshold: no data available

pH (undiluted): 10.0 – 11.0 (20 °C)

Melting point/freezing point: no data available
Initial boiling point and boiling range: no data available

Flash point: > 60 °C

Evaporation rate: no data available
Flammability (solid, gas): not applicable
Lower explosive limit: not applicable
Upper explosive limit: not applicable

Vapour pressure: no data available (... °C)

Vapour density: no data available

Relative density: 1.030 - 1.050 (20 °C)

according to Regulation (EC) No 1907/2006



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Solubility in water: completely soluble

Partition coefficient: not applicable

n-octanol/water

Auto-ignition temperature: not applicable

Decomposition temperature: no data available

Viscosity: no data available

Explosive properties: none Oxidising properties: none

9.2. Other information

Refractive index nD: 1.34477-1.34937 (20 °C) Electrical conductivity (5 g/l H_2O): 300-500 μ S/cm (20 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when handled and stored as intended.

10.2. Chemical stability

The product is stable when handled and stored as intended.

10.3. Possibility of hazardous reactions

None known

10.4. Conditions to avoid

None known

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

Does not decompose when used as intended.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Product

Acute toxicity - oral: Acute Toxicity Estimate $ATE_{mix} > 2000 \text{ mg/kg}$

=> no classification

Acute toxicity - dermal: Acute Toxicity Estimate $ATE_{mix} > 2000 \text{ mg/kg}$

=> no classification

Acute toxicity - inhalation: Acute Toxicity Estimate $ATE_{mix} > 20 \text{ mg/l}$

=> no classification

Ingredients

Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides (CAS No: 63449-41-2):

Acute toxicity - oral: No data available
Acute toxicity - dermal: No data available

according to Regulation (EC) No 1907/2006



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Skin corrosion/irritation

Product

Causes skin irritation. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye irritation. [calculation method]

Respiratory or skin sensitisation

Product

No data available.

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No data available.

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

SECTION 12: Ecological information

12.1. Toxicity

No classification. [calculation method]

12.2. Persistence and degradability

Biodegradability:

The product is biodegradable according to OECD criteria. The statement has been derived from the properties of the ingredients.

12.3. Bioaccumulative potential

No data available.

according to Regulation (EC) No 1907/2006



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12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII.

12.6. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal of the product

Product residues must be disposed of as hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. Do not dispose of via the waste water. Leave product in the original container as possible. Do not mix with other waste materials.

Waste codes / waste designations according to EWC

Product residues: 16 10 03* aqueous concentrates containing hazardous substances

Disposal of the packaging

Packaging contaminated with product is considered as hazardous waste and must be disposed of accordingly.

Waste codes / waste designations according to EWC

Contaminated packaging: 15 01 10* packaging containing residues of or contaminated by

hazardous substances

Recommendation

Contaminated packaging must be emptied optimally and can be recycled after appropriate cleaning (rinse with water).

SECTION 14: Transport information

14.0. Transport classification

No dangerous good in sense of the transport regulations in road traffic (ADR), railway traffic (RID), inland waterway traffic (ADN), maritime traffic (IMDG-Code) and air traffic (ICAO-TI/IATA-DGR).

14.1. UN number

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14.2. UN proper shipping name

_

14.3. Transport hazard class(es)

_

14.4. Packing group

-

14.5. Environmental hazards

_

according to Regulation (EC) No 1907/2006



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14.6. Special precautions for user

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

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14.8. Further information

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture EU-Regulations

REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer not applicable

REGULATION (EC) No 850/2004 on persistent organic pollutants and amending Directive 79/117/EEC not applicable

REGULATION (EU) No 649/2012 concerning the export and import of hazardous chemicals not applicable

DIRECTIVE 2012/18/EU (Seveso III Directive) on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC

not applicable

DIRECTIVE 2010/75/EU on industrial emissions (integrated pollution prevention and control)

not applicable

REACH - List of substances subject to authorisation (Annex XIV)

not applicable

REACH – Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

not applicable

COUNCIL DIRECTIVE 94/33/EC on the protection of young people at work

not applicable

COUNCIL DIRECTIVE 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

not applicable

15.2. Chemical safety assessment

For this mixture no chemical safety assessment has been carried out.

SECTION 16: Other information

16.1. Classification in accordance with Directive 1999/45/EC

Not required anymore as it is a new product.

according to Regulation (EC) No 1907/2006



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16.2. Label elements in accordance with Directive 1999/45/EC

Not required anymore as it is a new product.

16.3. Full text of code letters, hazard classes, R- and H-phrases

Code letters and categories of danger

C Corrosive

N Dangerous for the environment

Xi Irritant Xn Harmful

Hazard classes

Acute Tox. Acute toxicity
Aquatic Acute Acute aquatic hazard
Eye Dam. Serious eye damage
Eye Irrit. Eye irritation
Skin Corr. Skin corrosion
Skin Irrit. Skin irritation

R-phrases (Indications concerning special risks)

R21/22 Harmful in contact with skin and if swallowed.

R34 Causes burns.
R38 Irritating to skin.

R41 Risk of serious damage to eyes. R50 Very toxic to aquatic organisms.

H-phrases (Hazard 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.
H400 Very toxic to aquatic life.

16.4. Abbreviations and acronyms

ADN <u>A</u>ccord européen relatif au transport international des marchandises <u>d</u>angereuses par voie de

navigation intérieure (European Agreement concerning the International Carriage of

Dangerous Goods by Inland Waterways)

ADR <u>Accord européen relatif au transport international des marchandises d</u>angereuses par <u>route</u>

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

BGR <u>Berufsgenossenschaftliche Regeln</u> (English: Employers' liability insurance association rules)

BS <u>B</u>ritish <u>S</u>tandards

CAS Chemical Abstracts Service

CLP Regulation on Classification, Labelling and Packaging of Substances and Mixtures

[DE] National German regulations

DGUV <u>Deutsche Gesetzliche Unfallversicherung</u> (English: German statutory accident insurance)

EC <u>European Community</u>

EEC <u>European Economic Community</u>

EN European Standard
EU European Union

EWC <u>European Waste Catalogue</u>

GHS <u>G</u>lobally <u>H</u>armonized <u>S</u>ystem of Classification, Labelling and Packaging of Chemicals

GMBI <u>G</u>emeinsames <u>M</u>inisterial<u>bl</u>att (English: Joint Ministerial Gazette)

IATA-DGR <u>International Air Transport Association - Dangerous Goods Regulations</u>

according to Regulation (EC) No 1907/2006



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IBC-Code International Code for the Construction and Equipment of Ships carrying Dangerous

Chemicals in Bulk

ICAO-TI Technical Instructions For The Safe Transport of Dangerous Goods by Air

IMDG-Code International Maritime Code for Dangerous Goods

LGK <u>Lagerklasse</u> (English: Storage class)

MARPOL International Convention for the Prevention of Marine Pollution from Ships

OECD <u>Organization for Economic Co-operation and Development</u>

PBT Persistent, bioaccumulative and toxic

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID Règlement concernant le transport International ferroviaire de marchandises Dangereuses

(Regulations Concerning the International Carriage of Dangerous Goods by Rail)

TRGS Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances)

UN <u>U</u>nited <u>N</u>ations

UTC Coordinated Universal Time (French: Temps Universel Coordonné)

vPvB <u>Very persistent and very bioaccumulative</u>

16.5. Key literature references and sources for data

- Regulation (EC) No 1907/2006 (REACH), Annex II

- European Chemicals Agency (ECHA) Guidance on the compilation of safety data sheets; Version 2.1 (February 2014); http://echa.europa.eu/documents/10162/13643/sds en.pdf
- GISBAU (Hazardous substances information system of the BG BAU) course "safety data sheet";
 http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm
- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008 (04/2011);

http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

- European Chemicals Agency (ECHA), Registered substances;
 http://echa.europa.eu/information-on-chemicals/registered-substances
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; http://echa.europa.eu/information-on-chemicals/cl-inventory-database
- Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA):

 GESTIS database on hazardous substances and GESTIS International limit values for chemical agents;

 http://www.dejuv.de/dguv/ifa/index.jsp
- German Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and Information on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to Waters); http://webrigoletto.uba.de/rigoletto

16.6. Training advice

Provide adequate information, instructions and training for users.

16.7. Indication of changes

Recast of the safety data sheet. All sections have been revised according to Regulation (EC) No 1907/2006 (REACH) incl. Regulation (EU) No 453/2010. The product was reclassified in accordance with Regulation (EC) No 1272/2008 (CLP Regulation).

Changed formulation. Valid from LOT No. 665706.

The information given in the safety data sheet only apply to the described product in connection with its intended use. These information are based on the latest state of our knowledge at the time of revision. In particular, they describe our product under the aspect of its hazards and safety measures to be taken. They do not constitute any guarantee of product properties and quality features.