

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **Alpron**
Issue/Revision: 11.09.2015
Print date: 10.02.2016

Version: 1.0
Replaces version: of 07.09.2009

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

1.1 Product identifier

Trade name: **Alpron**

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

Relevant identified uses: Cleaning and disinfecting agent
Intended purpose: Concentrate for the continuous decontamination of water lines (including instruments and tumbler filler) in all medical and dental treatment units.
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]

The mixture is not classified as hazardous in the sense of Regulation (EC) No 1272/2008 [CLP].

Classification in accordance with Directive 1999/45/EC

see SECTION 16.1.

2.2. Label elements

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

Hazard pictograms: -
Signal word: -
Hazard components for labelling: -
H-phrases: -

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EUH-phrases: EUH208 Contains polyhexamethylenebiguanidehydrochloride. The concentrate may produce an allergic reaction.
EUH210 Safety data sheet available on request.

P-phrases: -

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 edetic acid, biguanide, tosylchloramide sodium, scents and flavouring substances in aqueous solution.

Hazardous ingredients

<i>Chemical name</i>	<i>Identification numbers</i>	<i>Classification in accordance with Directive 67/548/EEC</i>	<i>Classification in accordance with Regulation (EC) No 1272/2008</i>	<i>Weight %</i>
Disodium dihydrogenethylene-diaminetetra-acetate	CAS No: 139-33-3 EC No: 205-358-3 REACH Registration No: 01-2119486775-20-XXXX	Xn; R20	Acute Tox. 4; H332	≥ 1 - < 5
Guanidine, N,N'''-1,3-propanediyl-bis-, N-coco alkyl derivatives	CAS No: 98246-84-5 EC No: 308-757-1	Xn; R22 C; R34 N; R50	Acute Tox. 4; H302 Skin Corr. 1B; H314 Aquatic Acute 1; H400	< 0.2
Polyhexamethylenebiguanidehydrochloride	CAS No: 91403-50-8	T; R23-48/23 Xn; R22 Carc. Cat. 3; R40 Xi; R41 R43 N; R50/53	Acute Tox. 4; H302 Skin Sens. 1B; H317 Eye Dam. 1; H318 Acute Tox. 2; H330 Carc. 2; H351 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	< 0.2
Tosylchloramide-sodium	CAS No: 7080-50-4	Xn; R22 R31 C; R34 R42	Acute Tox. 4; H302 Skin Corr. 1B; H314 Resp. Sens. 1; H334 EUH031	< 0.2

Full text of code letters, hazard classes, R-, H- and EUH-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: Supply fresh air. In case of complaints consult a physician.

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- Following skin contact: By way of precaution, wash skin with water and soap. In case of skin reactions, consult a physician.
- Following eye contact: Flush eyes with flowing water for several minutes holding eyelids apart. Remove contact lenses, if present and easy to do.
- Following ingestion: Rinse mouth with water. Let drink water.

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

None known.

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

The product contains a source of phenylalanine.

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 (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x)

5.3. Advice for firefighters

- Special protective equipment: Not necessary
- 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

Not necessary

6.3. Methods and material for containment and cleaning up

Containment

Not necessary

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).

Other information

Inappropriate containment and cleaning methods are not known.

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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.

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.

Advice on common storage: Not necessary

Further information on storage conditions: Recommended storage temperature: 5 °C – 30 °C
Protect from frost and light.

Storage class ([DE] TRGS 510): LGK 12 Non-combustible liquids that are not assigned to any of the aforementioned LGK

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

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

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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

No special protective measures necessary.

Personal protective equipment

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

Skin protection:

Hand protection: Protective gloves according to EN 374 are recommended

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

Not necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	clear, yellowish liquid	
Odour:	of mint	
Odour threshold:	no data available	
pH (undiluted):	5.0 – 6.0	(20 °C)
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flash point:	not applicable	
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:	1.015 – 1.025	(20 °C)
Solubility in water:	completely soluble	
Partition coefficient:	not applicable	

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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: 1.3447-1.3463 (20 °C)
Electrical conductivity (undiluted): 13.50-14.50 mS/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 mg/kg
=> no classification
Acute toxicity - dermal: Acute Toxicity Estimate ATE_{mix} > 2000 mg/kg
=> no classification
Acute toxicity - inhalation: Acute Toxicity Estimate ATE_{mix} > 20 mg/l
=> no classification

Ingredients

Disodium dihydrogenethylenediaminetetraacetate (CAS No: 139-33-3):

Acute toxicity - inhalation: LC₅₀: 1000 – 5000 mg/m³; species: rat; 6 h; method: OECD 403

Guanidine, N,N''-1,3-propanediyl-bis-, N-coco alkyl derivatives (CAS No: 98246-84-5):

Acute toxicity - oral: LD₅₀: 500 - 2000 mg/kg; species: rat

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Polyhexamethylenebiguanidehydrochloride (CAS No: 91403-50-8):

Acute toxicity - inhalation: LC₅₀: 1.85 mg/l; species: rat

Skin corrosion/irritation

Product

No classification. [calculation method]

Serious eye damage/irritation

Product

No classification. [calculation method]

Respiratory or skin sensitisation

Product

No classification. [calculation method]

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No classification. [calculation method]

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No classification. [calculation method]

STOT-repeated exposure

Product

No classification. [calculation method]

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.

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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 non-hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. Do not mix with other waste materials.

Waste codes / waste designations according to EWC

Product residues: 16 10 02 aqueous liquid wastes other than those mentioned in 16 10 01

Disposal of the packaging

Waste codes / waste designations according to EWC

Contaminated packaging: 15 01 02 plastic packaging

Recommendation

Contaminated packaging must be emptied optimally and can be recycled.

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

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

-

14.5. Environmental hazards

-

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

-

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

Note: This is the previous classification; products with this classification can still be in the supply chain or on the market and are allowed to be sold until 01.06.2017.

The product is not classified as hazardous in the sense of Preparation Directive 1999/45/EC.

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

Note: This is the previous labelling; products with this labelling can still be in the supply chain or on the market and are allowed to be sold until 01.06.2017.

The product does not require labelling in the sense of Preparation Directive 1999/45/EC.

Danger symbols: -

Indications of danger: -

Hazard components
for labelling: -

R-phrases: -

S-phrases: -

Special labelling of certain preparations (Directive 1999/45/EC Annex V):

not necessary

Additional information: contains phenylalanine

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

Code letters and categories of danger

C	Corrosive
Carc. Cat. 3	Carcinogen category 3
N	Dangerous for the environment
T	Toxic
Xi	Irritant
Xn	Harmful

Hazard classes

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic hazard
Aquatic Chronic	Long-term aquatic hazard
Carc.	Carcinogenicity
Eye Dam.	Serious eye damage
Resp. Sens.	Respiratory sensitization
Skin Corr.	Skin corrosion
Skin Sens.	Skin sensitization
STOT RE	Specific target organ toxicity (repeated exposure)

R-phrases (Indications concerning special risks)

R20	Harmful by inhalation.
R22	Harmful if swallowed.
R23	Toxic by inhalation.
R31	Contact with acids liberates toxic gas.
R34	Causes burns.
R40	Limited evidence of a carcinogenic effect.
R41	Risk of serious damage to eyes.
R42	May cause sensitization by inhalation.
R43	May cause sensitisation by skin contact.
R48/23	Toxic: danger of serious damage to health by prolonged exposure through inhalation.
R50	Very toxic to aquatic organisms.
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H-phrases (Hazard statements)

H302	Harmful if swallowed.
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H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351	Suspected of causing cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H372	Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

EUH-phrases (Supplemental hazard information and label elements)

EUH031 Contact with acids liberates toxic gas.

16.4. Abbreviations and acronyms

ADN	<u>A</u> ccord européen relatif au transport international des marchandises <u>d</u> angereuses par voie de <u>n</u> avigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	<u>A</u> ccord européen relatif au transport international des marchandises <u>d</u> angereuses par <u>r</u> oute (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BGR	<u>B</u> erufsgenossenschaftliche <u>R</u> egeln (English: Employers' liability insurance association rules)
BS	<u>B</u> ritish <u>S</u> tandards
CAS	<u>C</u> hemical <u>A</u> bstracts <u>S</u> ervice
CLP	Regulation on <u>C</u> lassification, <u>L</u> abelling and <u>P</u> ackaging of Substances and Mixtures
[DE]	National German regulations
DGUV	<u>D</u> eutsche <u>G</u> esetzliche <u>U</u> nfall <u>v</u> ersicherung (English: German statutory accident insurance)
EC	<u>E</u> uropean <u>C</u> ommunity
EEC	<u>E</u> uropean <u>E</u> conomic <u>C</u> ommunity
EN	European Standard
EU	<u>E</u> uropean <u>U</u> nion
EWC	<u>E</u> uropean <u>W</u> aste <u>C</u> atalogue
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>b</u> latt (English: Joint Ministerial Gazette)
IATA-DGR	<u>I</u> nternational <u>A</u> ir <u>T</u> ransport <u>A</u> ssociation - <u>D</u> angerous <u>G</u> oods <u>R</u> egulations
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 <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods
LC ₅₀	Median lethal concentration
LD ₅₀	Median lethal dose
LGK	<u>L</u> ager <u>k</u> lasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
OECD	<u>O</u> rganization for <u>E</u> conomic <u>C</u> o-operation and <u>D</u> evelopment
PBT	<u>P</u> ersistent, <u>b</u> ioaccumulative and <u>t</u> oxic
REACH	<u>R</u> egistration, <u>E</u> valuation, <u>A</u> uthorisation and Restriction of <u>C</u> hemicals
RID	<u>R</u> èglement concernant le transport <u>I</u> nternational ferroviaire de marchandises <u>D</u> angereuses (Regulations Concerning the International Carriage of Dangerous Goods by Rail)
TRGS	<u>T</u> echnische <u>R</u> egeln für <u>G</u> efahr <u>s</u> toffe (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>V</u> ery <u>p</u> ersistent and <u>v</u> ery <u>b</u> ioaccumulative

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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.dguv.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).

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.
