

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **Alpron**
Issue/Revision: 08.05.2023

Version: 3.0
Replaces version: 2.0

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

1.1. Product identifier

Trade name: **Alpron**
UFI: not applicable

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

Relevant identified uses: Cleaning and disinfecting agent
Intended purpose: Liquid concentrate for the continuous maintenance of the water quality in procedural water lines (including instruments and tumbler filler) of medical and dental 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: info@alpro-medical.de
Internet: www.alpro-medical.de

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]

<i>Classification</i>	<i>Classification procedure</i>
Aquatic Chronic 3; H412	Calculation method

Full text of hazard classes as well as H-phrases: see under 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: H412 The concentrate is harmful to aquatic life with long lasting effects.

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EUH-phrases: EUH208 Contains polyhexamethylenebiguanidehydrochloride. The concentrate may produce an allergic reaction.

P-phrases: -

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 (see SECTION 12.5.)

The substances in the mixture have no endocrine disrupting properties according to Regulation (EC) No. 1907/2006, Annex XIV (see SECTION 11 and SECTION 12.6.).

They are not on the list of substances of very high concern for authorisation according to Regulation (EC) No 1907/2006, Article 59, paragraph 10).

No further hazards known.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Chemical characterisation: Mixture of edetic acid, biguanide, tosylchloramide sodium, scents and flavouring substances in aqueous solution.

Hazardous ingredients

Chemical name	Identification numbers	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Disodium dihydrogen-ethylenediaminetetraacetate	CAS No: 139-33-3 EC No: 205-358-3 REACH Registration No: 01-2119486775-20-XXXX	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	Acute Tox. 4; H302 Skin Corr. 1B; H314 Aquatic Acute 1; H400	< 0.2
Polyhexamethylenebiguanidehydrochloride	CAS No: 1802181-67-4 (32289-58-0)	Acute Tox. 4; H302 Skin Sens. 1B; H317 STOT SE 3; H335 Eye Dam. 1; H318 Acute Tox. 2; H330 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <i>M-Factor acute: 10</i> <i>M-Factor chronic: 10</i>	< 0.2
Tosylchloramide-sodium	CAS No: 7080-50-4	Acute Tox. 4; H302 Skin Corr. 1B; H314 Resp. Sens. 1; H334 EUH031	< 0.2

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Butanone	CAS No: 78-93-3 EC No: 201-159-0 Index No: 606-002-00-3 REACH Registration No: 01-2119457290-43-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	< 0.2
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Full text of hazard classes, H- and EUH-phrases: see SECTION 16.1.
Occupational exposure limits: see SECTION 8.1

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.
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 (CO ₂)
Unsuitable extinguishing media:	Full water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:	Carbon monoxide (CO), carbon dioxide (CO ₂), nitrogen oxides (NO _x), hydrogen chloride (HCl), chlorine (Cl ₂) and chlorine dioxide (ClO ₂)
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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.

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6.2. Environmental precautions

Do not discharge into drains or surface and ground water.

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.

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.

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 medicines, food, feed, cosmetics and stimulants.

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: store between +5 °C and +30 °C.
Protect from frost and light.

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]; 10.07.2015 [No 27]; www.baua.de

[DE] DGUV rules 207-206 – Prevention of chemical risks when handling disinfectants in health service, Issue: 2016.12; Source: www.dguv.de/publikationen

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Country	Limit values				Legal Basis	Remarks
	Long term (8 hours)		Short term (15 minutes)			
	ppm	mg/m ³	ppm	mg/m ³		
Butanone (CAS No: 78-93-3)						
EU	200	600	300	900	2000/39/EG	
UK	200	600	300	899	EH40	SK

Used abbreviations, symbols, numerals and explanations

SK Skin

Biological limit values

Country	Parameter	Limit value	Test material	Sampling time	Legal basis
Butanone (CAS No: 78-93-3)					
Germany	2-butanone	25mg/l	urine	the end of shift	TRGS 903
UK	2-butanone	70 µmol/l	urine	the end of shift	BMGV

Information on monitoring procedures

BS EN 482:2021-04; Title: Workplace exposure - Procedures for the determination of the concentration of chemical agents;
British version of EN 482:2021

BS EN 689:2018; 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 689:2018

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)

CEN/TR 17055:2017; Title: Workplace exposure. Measurement of chemical agents complying with the requirements given in EN 482 and either one of EN 838, EN 1076, EN 13205, EN 13890 and EN 13936.
Choice of procedures

ISO TR 14294:2011; Title: Workplace atmospheres. Measurement of dermal Exposure. Principles and methods

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 BS EN 166 are recommended

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Skin protection:

Hand protection:

Splash guard:

Protective gloves: Type C; permeation resistant at least 10 minutes

Permanent contact (> 480 min):

Protective gloves: Type A or B; Identification letters: G, E, A;
permeation resistant at least 30 minutes

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/ physical state:	clear, yellowish liquid	
Odour:	of mint	
Odour threshold:	no data available	
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flammability:	not applicable	
Lower explosive limit:	not applicable	
Upper explosive limit:	not applicable	
Flash point:	not applicable	
Auto-ignition temperature:	no data available	
pH (undiluted):	5.0 – 6.0	(20 °C)
Kinematic viscosity:	no data available	
Solubility in water:	completely soluble	
Partition coefficient: n-octanol/water	not applicable	
Vapour pressure:	no data available	(... °C)
Density:	1.015 – 1.025 g/cm ³	(20 °C)
Relative vapour density:	no data available	
Particle characteristics:	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive substances/mixtures and products containing explosives:	not applicable
Flammable gases:	not applicable

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Aerosols:	not applicable
Oxidising gases:	not applicable
Gases under pressure:	not applicable
Flammable liquids:	not applicable
Flammable solids:	not applicable
Self-reactive substances and mixtures:	not applicable
Pyrophoric liquids:	not applicable
Pyrophoric solids:	not applicable
Self-heating substances and mixtures:	not applicable
Substances and mixtures, which emit flammable gases in contact with water:	not applicable
Oxidising liquids:	not applicable
Oxidising solids:	not applicable
Organic peroxides:	not applicable
Substances and mixtures corrosive to metals:	not applicable
Desensitised explosives:	not applicable

9.2.2. Other safety characteristics

Electrical conductivity (undiluted): 13.00 - 15.00 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

No material incompatibilities when used as intended.

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

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=> 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

Polyhexamethylenebiguanidehydrochloride (CAS No: 1802181-67-4):

Acute toxicity - inhalation: LC₅₀: 1.61 mg/l; species: rat; method: OECD 403

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 data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No classification. [calculation method]

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

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Information on other hazards

Endocrine disrupting properties:

No substances are contained that have endocrine disrupting properties for humans.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. [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.

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. Endocrine disrupting properties

No substances are contained that have endocrine disrupting properties for non-target organisms.

12.7. 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 01* aqueous liquid wastes 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).

From a dilution to 10 % or more, the mixture is no longer classified as a hazardous substance.

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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

-

14.7. Maritime transport in bulk according to IMO instruments

-

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 2019/1021 on persistent organic pollutants
not applicable

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

REGULATION (EU) No 648/2004 on detergents
cationic surfactants: < 5 %
EDTA: < 5 %
Disinfectants
Perfumes

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

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

VOC content: < 1 %

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

National regulations (Great Britain)

EH40

see section 8.1

BMGV

see section 8.1

15.2. Chemical safety assessment

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

SECTION 16: Other information

16.1. Full text of hazard classes and H-phrases

Hazard classes

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

H-phrases (Hazard statements)

H302	Harmful if swallowed.
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.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

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EUH-phrases (Supplemental hazard information and label elements)

EUH031 Contact with acids liberates toxic gas.

16.2. 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)
BMGV	Biological Monitoring Guidance Values
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
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
ICAO-TI	Technical Instructions For The Safe Transport of Dangerous Goods by Air
IMDG-Code	<u>I</u> nternational <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)
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
ppm	<u>P</u> arts <u>p</u> er <u>m</u> illion
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)
VOC	Volatile Organic Compounds
vPvB	<u>V</u> ery persistent and <u>v</u> ery <u>b</u> ioaccumulative

16.3. 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 4.0 (December 2022); <https://echa.europa.eu/documents>
- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) – Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008; Version 4.2 (03/2021); <https://echa.europa.eu/documents>
- European Chemicals Agency (ECHA), Registered substances; <https://echa.europa.eu/information-on-chemicals/registered-substances>

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<https://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;
<https://www.dguv.de/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); <https://webrigoletto.uba.de/rigoletto>

16.4. Methods according to Article 9 of Regulation (EC) No 1272/2008 for the evaluation of information for classification purposes

Calculation method according to the criteria in Annex I 1272/2008.
Flash point according to EN ISO 2719:2002.
pH value measurement.
Material compatibility and corrosiveness in practical tests

16.5. Training advice

Provide adequate information, instructions and training for users.

16.6. Indication of changes

A dash in the left hand margin indicates an amendment from the previous version.

The information given in the safety data sheet only applies to the described product in connection with its intended use. This information is based on the latest state of our knowledge at the time of revision. In particular, it describes our product under the aspect of its hazards and safety measures to be taken. It does not constitute any guarantee of product properties and quality features.
