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 decontaminating 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

Supplier:
Biodegree PTY. LTD.
2/359 Alfred Street North
Neutral Bay NSW 2089 (Australia)
Telephone: +61 499145331
E-mail: info@biodegree.com.au

Manufacturer:
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
or **Poisons Information Centre (Phone Australia 131 126) (24h emergency call)**

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*
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.
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.

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

Chemical name	*Identification numbers*	*Classificationin accordance with Regulation (EC) No 1272/2008*	*Weight %*
Disodium dihydrogen-ethylenediaminetetra-acetate	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
Polyhexamethylene-biguanidehydro-chloride	CAS No: 1802181-676-4 (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 *M-Factor acute: 10* *M-Factor chronic: 10*	< 0.2
Tosylchloramide-sodium	CAS No: 7080-50-4	Acute Tox. 4; H302 Skin Corr. 1B; H314 Resp. Sens. 1; H334 EUH031	< 0.2

Full text of hazard classes, H- and EUH-phrases: see SECTION 16.1.

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)

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

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.

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 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: GMBl 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

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

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:	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: n-octanol/water	not applicable	
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: LC_{50}: 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: LD_{50}: 500 - 2000 mg/kg; species: rat

Polyhexamethylenebiguanidehydrochloride (CAS No: 1802181-67-4):
Acute toxicity - inhalation: LC_{50}: 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.

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. 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).

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

-

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. 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.

EUH-phrases (Supplemental hazard information and label elements)

EUH031	Contact with acids liberates toxic gas.

16.2. Abbreviations and acronyms

ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BGR	Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)
BS	British Standards
CAS	Chemical Abstracts Service
CLP	Regulation on Classification, Labelling and Packaging of Substances and Mixtures
[DE]	National German regulations
DGUV	Deutsche Gesetzliche Unfallversicherung (English: German statutory accident insurance)

EC	European Community
EEC	European Economic Community
EN	European Standard
EU	European Union
EWC	European Waste Catalogue
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
GMBl	Gemeinsames Ministerialblatt (English: Joint Ministerial Gazette)
IATA-DGR	International Air Transport Association - Dangerous Goods Regulations
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
LC_{50}	Median lethal concentration
LD_{50}	Median lethal dose
LGK	Lagerklasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
OECD	Organization for Economic Co-operation and Development
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	United Nations
UTC	Coordinated Universal Time (French: Temps Universel Coordonné)
vPvB	Very persistent and very bioaccumulative

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 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

16.4. Training advice

Provide adequate information, instructions and training for users.

16.5. 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.
