according to Regulation (EC) No 1907/2006



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

1.1. Product identifier

Trade name: Bilpron®

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

Relevant identified uses: Cleaning and decontaminating agent

Intended purpose: Solution ready for use for the decontamination and

prevention of biofilm formation in procedural water lines

of medical and dental units.

Uses advised against: None at intended use.

The product is intended for professional users. Note:

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]

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

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2.2. Label elements

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

The mixture does not require labelling in the sense of Regulation (EC) No 1272/2008 [CLP].

Hazard pictograms:

Signal word:

Hazard components

for labelling: H-phrases: 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 propylene glycol, parabens, biguanides and complexing

agents in aqueous solution.

Hazardous ingredients

Does not contain hazardous ingredients above concentration limit values fixed in Regulation (EC) No 1907/2006.

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: No special measures necessary.

Flush eyes with flowing water for several minutes holding eyelids apart. Following eye contact:

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

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

carbon dioxide (CO₂)

according to Regulation (EC) No 1907/2006



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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)

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.

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.

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

Not necessary

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

according to Regulation (EC) No 1907/2006



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Further information on storage conditions: Recommended storage temperature: -10 $^{\circ}$ C - 30 $^{\circ}$ C

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

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: Not necessary when used as intended.

Skin protection:

Hand protection:

Other skin protection:

Not necessary when used as intended.

Not necessary when used as intended.

Not necessary when used as intended.

Thermal hazards:

No special protective measures necessary.

Environmental exposure controls

Not necessary

according to Regulation (EC) No 1907/2006



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

clear, blue liquid Appearance: Odour: characteristic Odour threshold: no data available

5.5 - 6.5pH (undiluted): (20 °C)

Melting point/freezing point: no data available Initial boiling point and boiling range: no data available Flash point: not applicable no data available Evaporation rate: Flammability (solid, gas): not applicable Lower explosive limit: not applicable Upper explosive limit: not applicable

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

no data available Vapour density:

Relative density: 0.995 - 1.005(20 °C)

Solubility in water: completely soluble

Partition coefficient: not applicable

n-octanol/water

Auto-ignition temperature: not applicable Decomposition temperature: no data available no data available Viscosity:

Explosive properties: none Oxidising properties: none

9.2. Other information

Refractive index nD: 1.3355-1.3370 (20 °C) Electrical conductivity (undiluted): 920-1020 μS/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

according to Regulation (EC) No 1907/2006



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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

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.

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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.

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).

according to Regulation (EC) No 1907/2006



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14.1.UN number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

-

14.4. Packing group

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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

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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

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

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

not applicable

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

according to Regulation (EC) No 1907/2006



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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 code letters, hazard classes, R- and H-phrases

Hazard classes

H-phrases (Hazard statements)

TRGS UN

United Nations

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	Accord 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	Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)
BS	British Standards
CLP	Regulation on Classification, Labelling and Packaging 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>European Community</u>
EEC	<u>European Economic Community</u>
EN	European Standard
EU	<u>E</u> uropean <u>U</u> nion
EWC	<u>European Waste Catalogue</u>
GHS	Globally Harmonized System 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	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 <u>I</u> nternational <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods	
LGK	<u>Lagerklasse</u> (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	<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>Technische Regeln für Gefahrstoffe</u> (English: Technical Rules for Hazardous Substances)

according to Regulation (EC) No 1907/2006



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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 apply 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.