according to regulation (EC) 1907/2006 (REACH)



Trade name: Alprox Page 1/5

Revised at: 23.11.2010 Print date: 25.11.2010

1. Identification of the substance/preparation and of the company/undertaking

Trade name: Alprox

Recommended use: Universal rinsing solution ready for use for application in mouth

rinsing and ultrasonic devices.

Effect of the preparation: Cleansing and preservative agent

Manufacturer: ALPRO MEDICAL GMBH

Mooswiesenstr. 9

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

Technical contact point: +49 7725 9392-0

Emergency phone: +49 7725 9392-0 (business hours)

+49 761 19240 Poisoning-information-central, Freiburg (24h emergency call)

2. Hazards identification

This product does not require labelling in terms of preparation guideline 1999/45/EC.

3. Composition/information on ingredients

Chemical characterization: Mixture of edetin acid, tosylchloramide sodium, phenylalanine,

perfume and flavour substances in aqueous solution.

Does not contain hazardous ingredients above concentration limits fixed in preparation guideline 1999/45/EC.

4. First aid measures

General information: Note precautions for self-protection.
On inhalation: No special measures necessary.
On contact with skin: No special measures necessary.

On contact with the eyes: Rinse the eyes with water with the eyelids open for a sufficient length of

ime.

If swallowed: Drink plenty of water.

Information for the doctor: First aid, decontamination, symptomatic treatment.

according to regulation (EC) 1907/2006 (REACH)



Trade name: **Alprox Page 2/5**

Revised at: 23.11.2010 Print date: 25.11.2010

5. Fire-fighting measures

Suitable extinguishing media: Water, foam, dry fire-extinguishing media, carbon dioxide

Extinguishing media which must not be used

for safety reasons: None known

Special exposure hazards arising from the substance or preparation itself, combustion

products, resulting gases: None known Special protective equipment for firefighting: Not necessary

Additional information: Cool endangered containers with water spray jet and if

possible remove off fire area.

6. Accidental release measures

Personal precautions: Use personal protective clothing. High risk of slipping due

to leakage/spillage of product.

Environmental precautions: Contain spillage with absorbing material, e.g. with sand.

Methods for cleaning up/taking up: Treat recovered material as prescribed in: Disposal

considerations.

7. Handling and storage

Hints for safe handling: Not necessary

Hints for protection against fire and explosion: Product is not flammable.

Further information: Not necessary

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

Hints on storage assembly: Not necessary Further information on storage conditions: Not necessary LGK 10

Storage class:

8. Exposure controls / Personal protection

Constituents with occupational exposure limits rsp. biological occupational exposure limits requiring monitoring:

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

General health and safety measures:

Do not eat, drink, smoke while working.

Wash hands before breaks and on finishing work.

Preventive skin protection using barrier ointment.

Keep away of foods and drinks.

Avoid contact with eyes, skin and clothing.

Avoid inhalation of aerosols and vapours.

according to regulation (EC) 1907/2006 (REACH)



Trade name: Alprox Page 3/5

Revised at: 23.11.2010 Print date: 25.11.2010

Personal protection equipment:

Respiratory protection: Not necessary.
Hand protection: Not necessary.
Eye protection: Not necessary.
Protective clothing: Not necessary.

9. Physical and chemical properties

Form: liquid

Colour: turquoise, clear

Odour: of mint

pH-value (undiluted): 5,0-6,0 (20°C)

Boiling point/Boiling range: not relevant to safety

Melting point/Melting range: not relevant to safety

Flash point (DIN, TRbF): >55°C

Flammability (solid, gases): not determinable

Explosive properties: none
Lower explosion limit: none
Upper explosion limit: none

Ignition temperature: not necessary

Oxidizing properties: none

Vapour pressure: not necessary at ... $^{\circ}$ C Density: 0,995-1,000 g/cm³ at 20 $^{\circ}$ C Bulk density: not determinable at ... $^{\circ}$ C

Solubility in water: soluble in ethanol: soluble

in hexan: not soluble

Partition coefficient: not necessary (n-octanol/water)

Viskosity (sort): not necessary at ... $^{\circ}$ C Electrical conductivity (undiluted): 900-1000 μ S/cm (20 $^{\circ}$ C) Refractive index nD: 1,3330-1,3335 (20 $^{\circ}$ C)

Optical rotation αD : not necessary

10. Stability and reactivity

Conditions to avoid: No hazardous decomposition products if stored and handled as

prescribed.

Materials to avoid: No hazardous reactions with other substances known.

Hazardous decomposition products: No decomposition if used as prescribed.

according to regulation (EC) 1907/2006 (REACH)



Trade name: Alprox Page 4/5

Revised at: 23.11.2010 Print date: 25.11.2010

11. Toxicological information

Acute toxicity: No acute toxicity known.

Primary irritant effect on the skin: No primary irritant effect on the skin known.

Primary irritant effect on the eye: No primary irritant effect on the eye known.

Mutagenic potential: No mutagenic potential known.
Sensitization: No sensitizing effects known.

The product was classified on the basis of the calculation procedure of the preparation directive 1999/45/EC.

Based on manufacturer data of the main components the acute toxicity, the skin irritation, the mucous membrane irritation and the mutagenic potential of the preparation were evaluated. However, some data are not complete regarding particular main components. Nevertheless according to the experience of the manufacturer there are no other hazards expected than those which are already mentioned on the label.

12. Ecological information

Ecotoxicity: Inhibition of degradation activity in activated sludge is not to be

anticipated during correct introduction of low concentrations.

Persistence and degradation: Ingredients are biodegradable.

Other adverse effects: No other adverse effects known.

Further information: Do not allow product to reach ground water or waters and do not

empty undiluted product into sewers.

13. Disposal considerations

Disposal of the product:

In the EC member states there are no standardized regulations for the disposal of chemicals. In Germany the law of the cycle of economy and waste (KrW/AbfG) prescribes the principle of utilization and therefore a distinction must be made between "waste for utilization" and "waste for removal". Furthermore special cases – particularly in case of delivery – are also regulated by the federal states. Please contact the corresponding office (authority or waste disposal company) who will inform you about the utilization or removal.

Waste code no.*: 16 10 02

Disposal of uncleaned as well as completely emptied packings:

Disposal according to official regulations. Contaminated packings are to be treated like the substance.

Waste code no.*: 15 01 02

Further information:

If there is no official regulation, non-contaminated packings can be treated like domestic waste or can be recycled.

*Waste code no.: Waste incurred is classified following the code of the European waste register

according to kind of waste and branch.

according to regulation (EC) 1907/2006 (REACH)



Trade name: Alprox Page 5/5

Revised at: 23.11.2010 Print date: 25.11.2010

14. Transport information

No hazardous material as defined by the transport regulations (ADR/RID, IMDG-Code, ICAO-TI/IATA-DGR)

15. Regulatory information

Labelling

Code letter: Hazard designation: contains: R-phrases: S-phrases: -

Special labelling of certain preparations (preparation directive 1999/45/EC annex V):

not necessary

Additional information: contains phenylalanine

National regulations (Germany)

Restrictions of occupation: None

Störfallverordnung: -

Classification according to VbF: Not subject to the VbF

Technische Anleitung Luft:

Water hazard class: WGK 0 (not water hazardous); self-classification

16. Other information

Further information:

This information is based on our present knowledge and describes the safety measures which are to be taken for this product. However, this shall not constitute a guarantee for any product features.

Marking of changes:

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

New: Layout of the safety data sheet according to REACH.