

# Safety Data Sheet

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



Trade name: **AlproZyme**  
Revised at: 15.03.2011  
Print date: 07.04.2011

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

Trade name: **AlproZyme**

Recommended use: Alkaline-enzymatic cleaning granulate for the processing of medical and dental instruments and endoscopes. Useable in soaking bath, ultrasonic cleaner and thermal washer.

Effect of the preparation: Cleansing agent, enzymatic

Manufacturer: ALPRO MEDICAL GMBH  
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Email: alpro@alpro-medical.de  
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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

R34 Causes burns.  
R37 Irritating to respiratory system.  
R42 May cause sensitization by inhalation.

## 3. Composition/information on ingredients

Chemical characterization: Mixture of substances listed below with nonhazardous additions.

<i>Hazardous ingredients</i>	<i>CAS-No.</i>	<i>Weight-%</i>	<i>Code letter</i>	<i>R-phrases*</i>
Disodiummetasilicate-pentahydrate	10213-79-3	>30%	C	34, 37
Sodium carbonate	497-19-8	1-5%	Xi	36
Protease enzyme protein (Subtilisin)	9014-01-1	1-5%	Xn	37/38, 41, 42

\*Full text of R-phrases: see under section 16

## 4. First aid measures

General information: Remove contaminated, saturated clothing immediately. Note precautions for self-protection.

On inhalation: Move affected person into fresh air and keep still and warm. Seek medical advice.

On contact with skin: Wash off immediately with soap and water. In case of skin reactions, seek medical advice.

On contact with the eyes: Rinse the eyes with water with the eyelids open for a sufficient length of time, then seek ophthalmological advice immediately.

If swallowed: Rinse out mouth and then drink plenty of water. Do not induce vomiting. Seek medical advice.

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

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## 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. Avoid particular generation of dust.
Environmental precautions:	Do not empty into drains/surface water/ground water.
Methods for cleaning up/taking up:	Treat recovered material as prescribed in: Disposal considerations.

## 7. Handling and storage

Hints for safe handling:	Avoid contact with skin and eyes. Avoid generation of dust.
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. Store in a dry place.
Hints on storage assembly:	Keep away from foodstuffs, beverages and animal feedstocks.
Further information on storage conditions:	Not necessary
Storage class:	LGK 8AS combustible corrosive substances (solid)

## 8. Exposure controls / Personal protection

### Constituents with occupational exposure limits resp. 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.

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## Personal protection equipment:

Respiratory protection:	Not necessary if handled cautiously.
Hand protection:	E.g. natural rubber- or PVC-gloves.
Eye protection:	Tightly sealed goggles.
Protective clothing:	Usual protective clothing (Labor smock).

## 9. Physical and chemical properties

Form:	granular powder	
Colour:	white	
Odour:	characteristic	
pH-value (5 g/l H <sub>2</sub> O):	11,5-12,5	(20°C)
Boiling point/Boiling range:	not relevant to safety	
Melting point/Melting range:	not relevant to safety	
Flash point:	>55°C	
Flammability (solid, gases):	not necessary	
Explosive properties:	none	
Lower explosion limit:	none	
Upper explosion limit:	none	
Ignition temperature:	not necessary	
Oxidizing properties:	none	
Vapour pressure:	not necessary	at ...°C
Density:	not determinable	at ...°C
Bulk density:	ca. 900 kg/m <sup>3</sup>	at 20°C
Solubility in water:	soluble	
in ethanol:	soluble	
in hexan:	not soluble	
Partition coefficient:	not necessary	(n-octanol/water)
Viscosity (sort):	not necessary	at ...°C
Electrical conductivity (5 g/l H <sub>2</sub> O):	5500-6500 µS/cm	(20°C)
Refractive index n <sub>D</sub> :	not necessary	
Optical rotation α <sub>D</sub> :	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.

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## 11. Toxicological information

Acute toxicity:	No acute toxicity known.
Primary irritant effect on the skin:	Causes burns.
Primary irritant effect on the eye:	Causes burns.
Mutagenic potential:	No mutagenic potential known.
Sensitization:	May cause sensitization by inhalation.

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 or can be precipitated harmlessly.
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.\*: 07 06 99

### 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 10

### 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.

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## 14. Transport information

### Land transport ADR/RID and GGVSE

UN-No.: 3253  
Class: 8  
Packing Group: III  
Proper Shipping Name:  
DISODIUMTRIOXOSILICATE

### Inland waterway craft ADN/ADNR

Not classified.

### Marine transport IMDG/GGVSee

UN-No.: 3253  
Class: 8  
Packing Group: III  
EmS-No.: F-A; S-B  
Proper Shipping Name:  
DISODIUMTRIOXOSILICATE

### Air transport ICAO-TI/IATA-DGR

UN-/ID-No.: 3253  
Class: 8  
Packing Group: III  
Proper Shipping Name:  
DISODIUMTRIOXOSILICATE

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## 15. Regulatory information

### Labelling

Code letter:	C
Hazard designation:	Corrosive
contains:	Disodiummetasilicate-pentahydrate, Protease enzyme protein (Subtilisin)
R-phrases:	R34 Causes burns. R37 Irritating to respiratory system. R42 May cause sensitization by inhalation.
S-phrases:	S22 Do not breathe dust. S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S28 After contact with skin, wash immediately with water and soap. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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

not necessary

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## National regulations (Germany)

Restrictions of occupation:	Juvenile in relation to § 22 JArbSchG
Störfallverordnung:	-
Classification according to VbF:	Not subject to the VbF
Technische Anleitung Luft:	-
Water hazard class:	WGK 2 (water hazardous); self-classification

## 16. Other information

### Full text of R-phrases appearing in section 3: (This is not the classification of the product AlproZyme!)

- R34 Causes burns.
- R36 Irritating to eyes.
- R37 Irritating to respiratory system.
- R37/38 Irritating to respiratory system and skin.
- R41 Risk of serious damage to eyes.
- R42 May cause sensitization by inhalation.

### 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.