

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproZyme**
Issue/Revision: 03.12.2021
Print date: 03.12.2021

Version: 2.01
Replaces version: 2.0

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

1.1. Product identifier

Trade name: **AlproZyme**

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

Relevant identified uses: Cleaning agent, enzymatic
Intended purpose: Alkaline-enzymatic cleaning granulate for the pre-cleaning and pre-disinfection for the processing of medical and dental instruments, rotating precision instruments and endoscopes. Useable by soaking bath method as well as in ultrasonic devices and washer-disinfectors.
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: 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

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>
Skin Corr. 1B; H314	Calculation method
STOT SE 3; H335	Calculation method

Full text of hazard classes as well as H-phrases: see under SECTION 16.1.

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2.2. Label elements

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

Hazard pictograms:



Signal word:

Danger

Hazard components
for labelling:

Disodium metasilicate (6834-92-0)

H-phrases: H314
H335

Causes severe skin burns and eye damage.
May cause respiratory irritation.

EUH-phrases: EUH208

Contains Subtilisin. May produce an allergic reaction.

P-phrases: P260
P280

Do not breathe dust.
Wear protective gloves/protective clothing/eye protection/face
protection.

P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated
clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove
contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/ doctor.

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 substances listed below with non-hazardous additions.

Hazardous ingredients

Chemical name	Identification numbers	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Disodium metasilicate	CAS No: 6834-92-0 EC No: 229-912-9 Index No: 014-010-00-8 REACH Registration No: 01-2119449811-37-XXXX	Skin Corr. 1B; H314 STOT SE 3; H335	≥ 50
Subtilisin	CAS No: 9014-01-1 EC No: 232-752-2 Index No: 647-012-00-8 REACH Registration No: 01-2119480434-38-XXXX	Acute Tox. 4; H302 STOT SE 3; H335 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1; H334 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	≥ 0.2 - < 1

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

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SECTION 4: First aid measures

4.1. Description of first aid measures

General information:	First aider: Pay attention to self-protection! Remove contaminated, saturated clothing immediately.
Following inhalation:	Move affected person into fresh air and keep still and warm. Seek medical advice.
Following skin contact:	Wash skin immediately with plenty of water and soap. In case of skin reactions, consult a physician.
Following eye contact:	Flush eyes immediately with flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Consult an ophthalmologist.
Following ingestion:	Rinse mouth with water. Let drink plenty of water. Do not induce vomiting (risk of perforation). Consult a physician immediately.

4.2. Most important symptoms and effects, both acute and delayed

Causes severe skin burns and eye damage. May cause respiratory irritation. May produce an allergic reaction.

4.3. Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide (CO₂)

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), nitrogen oxides (NO_x)

5.3. Advice for firefighters

Special protective equipment: Wear self-contained breathing apparatus.

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. Do not breathe dust. Avoid formation of dust. Provide adequate ventilation. Evacuate danger area. Observe emergency plans. Consult experts.

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. Environmental precautions

Do not discharge into drains or rivers.

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6.3. Methods and material for containment and cleaning up

Containment

For large spills, cover spilled material with a plastic cover in order to prevent spreading and to keep the powder dry.

Cleaning up

Take up mechanically. Avoid formation of dust. 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. Avoid formation of dust. Keep container tightly closed.

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. Keep container tightly closed.

Advice on common storage: Keep away from food, drink and animal feedingstuffs.

Further information on storage conditions: Not necessary

Storage class ([DE] TRGS 510): LGK 8B Non-combustible corrosive hazardous substances

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.

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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

The eyewash station (or eyewash bottle) and emergency shower must be located near the workplace.

Personal protective equipment

Eye/face protection:	Safety glasses with side protection according to EN 166
Skin protection:	
Hand protection:	Protective gloves according to EN 374 <u>Splash guard:</u> Disposable gloves made of nitrile rubber (thickness 0.11 mm) <u>Permanent contact (> 480 min):</u> Protective gloves made of nitrile rubber (thickness 0.40 mm)
Other skin protection:	Long-sleeved protective clothing (lab coat)
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:	white, granular powder
Odour:	characteristic
Odour threshold:	no data available
pH (5 g/l H ₂ O):	11.5 – 12.5 (20 °C)
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	no data available
Flash point:	not applicable
Evaporation rate:	not applicable
Flammability (solid, gas):	no data available

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Lower explosive limit:	not applicable	
Upper explosive limit:	not applicable	
Vapour pressure:	not applicable	
Vapour density:	not applicable	
Relative density:	no data available	(... °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:	1.3330 – 1.3342	(20 °C)
Electrical conductivity (5 g/l H ₂ O):	5000 – 6000 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

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} = 2080 mg/kg => no classification
Acute toxicity - dermal:	Acute Toxicity Estimate ATE _{mix} > 2000 mg/kg => no classification

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Acute toxicity - inhalation: Acute Toxicity Estimate ATE_{mix} > 20 mg/l
=> no classification

Ingredients

Disodium metasilicate (CAS No: 6834-92-0):

Acute toxicity - oral: LD₅₀: 1152 mg/kg; species: rat; ECHA: oral.001

Subtilisin (CAS No: 9014-01-1):

Acute toxicity - oral: LD₅₀: 1800 mg/kg; species: rat; ECHA: oral.001

Skin corrosion/irritation

Product

Causes severe skin burns. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye damage. [calculation method]

Respiratory or skin sensitisation

Product

The mixture is not classified as sensitising but it contains Subtilisin at a concentration between 0.2 and 1.0%. Label elements in accordance with Regulation (EC) No 1272/2008 Annex II, 2.8.:
„Contains Subtilisin. May produce an allergic reaction.“

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

May cause respiratory irritation. [calculation method]

Ingredients

Disodium metasilicate (CAS No: 6834-92-0):

May cause respiratory irritation.

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

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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.

Disodium metasilicate as inorganic substance is not subject to biodegradation.

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: 07 06 99* wastes not otherwise specified

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

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).

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14.1. UN number

UN 3253

14.2. UN proper shipping name

ADR/RID/ADN

DISODIUM TRIOXOSILICATE

IMDG-Code/ICAO-TI/IATA-DGR

DISODIUM TRIOXOSILICATE

14.3. Transport hazard class(es)

Class: 8
Subsidiary risk(s): -

14.4. Packing group

III

14.5. Environmental hazards

ADR/RID/ADN

Environmentally Hazardous: No

IMDG-Code

Marine Pollutant: No

14.6. Special precautions for user

Not necessary.

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

Not applicable for product as supplied.

14.8. Further information

Transport category according to ADR section 1.1.3.6: 3
Maximum total quantity per transport unit according to ADR section 1.1.3.6: 1000 kg
Limited quantity (Maximum quantity per inner packaging) according to ADR/RID/ADN/IMDG-Code: 5 kg
Classification code according to ADR/RID/ADN: C6
Hazard identification number according to ADR/RID: 80
Tunnel restriction code according to ADR/RID: E
Segregation group according to IMDG-Code section 5.4.1.5.11.1: IMDG-Code- Segregation group 18 – alkalis
EmS codes: F-A, S-B

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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

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

Observe employment restrictions for juveniles.

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 Irrit.	Skin irritation
STOT SE	Specific target organ toxicity (single exposure)

H-phrases (Hazard statements)

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.

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H315	Causes skin irritation.
H318	Causes serious eye damage.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.

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)
BGR	<u>B</u> erufsgenossenschaftliche <u>R</u> egeln (English: Employers' liability insurance association rules)
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
EmS	<u>E</u> mergency <u>S</u> chedules (Emergency response procedures for ships carrying dangerous goods)
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
GHS	<u>G</u> lobally <u>H</u> armonized <u>S</u> ystem of Classification, Labelling and Packaging of Chemicals
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
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 <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods
LD ₅₀	Median lethal dose
LGK	<u>L</u> ager <u>k</u> lasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
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
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)
vPvB	<u>V</u> ery <u>p</u> ersistent 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 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)

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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. The 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.
