according to Regulation (EC) No 1907/2006



Version: 3.0

Trade name: BRS® PreCleaner

Issue/Revision: 26.06.2023 Replaces version: 2.1

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

1.1. Product identifier

Trade name: BRS® PreCleaner

UFI: Q5TN-5263-800C-0X75

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

Relevant identified uses: Cleaning agent, enzymatic

Intended purpose: Cleaning powder for the precleaning of the procedural

water lines of 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

Manufacturer/Supplier: ALPRO MEDICAL GMBH

Mooswiesenstraße 9 D-78112 St. Georgen

Telephone: +49 7725 9392-0 Telefax: +49 7725 9392-91 E-mail: info@alpro-medical.de Internet: www.alpro-medical.de

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

National Poisons Information Centre (UK): +44 344 892 0111

National Poisons Information Service (NPIS) (24 h / 7 d), Medical Professionals Only

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
Skin Corr. 1B; H314	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:



according to Regulation (EC) No 1907/2006



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Signal word: Danger

Hazard components

for labelling: Disodium metasilicate (6834-92-0)

H- phrases: H314 Causes severe skin burns and eye damage.

P- phrases: P260 Do not breathe dust.

P280 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 (see SECTION 12.5.).

The substances in the mixture do not have any endocrine disrupting properties according to Regulation (EC) No. 1907/2006, Annex XIV (see Section 11 and Section 12.6.). They are not on the list of substances of very high concern for authorization according to Regulation (EC) No. 1907/2006, Article 59, Paragraph 10).

No further hazards known.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical characterisation: Mixture of substances listed below with non-hazardous additions.

Gefährliche Inhaltsstoffe

Chemical name	Identification numbers	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Sodium carbonate	CAS No: 497-19-8 EC No: 207-838-8 Index No: 011-005-00-2 REACH Registration No: 01-2119485498-19-XXXX	Eye Irrit. 2; H319	≥ 50
Dinatriummetasilikat	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	≥ 15 - < 20

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

Occupational exposure limits: see SECTION 8.1

according to Regulation (EC) No 1907/2006



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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.

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)

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 surface and ground water.

according to Regulation (EC) No 1907/2006



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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 medicines, food, feed, cosmetics and stimulants.

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: Keep away from sunlight.

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]; 10.07.2015 [No 27]; www.baua.de.
- [DE] DGUV rules 207-206 Prevention of chemical risks when handling disinfectants in health service, Issue: 2016.12; 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.

Angaben über Überwachungsverfahren

BS EN 482:2021-04; Title: Workplace exposure - Procedures for the determination of the concentration of chemical agents; British version of EN 482:2021

BS EN 689:2018; 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 689:2018

CEN/TR 17055:2017; Title: Workplace exposure. Measurement of chemical agents complying with the requirements given in EN 482 and either one of EN 838, EN 1076, EN 13205, EN 13890 and EN 13936. Choice of procedures

ISO TR 14294:2011; Title: Workplace atmospheres. Measurement of dermal Exposure. Principles and methods

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 BS EN 166

Skin protection:

Hand protection: Protective gloves according to BS EN ISO 374-1 and BS EN 21420

Splash guard:

Protective gloves: type C; permeation-resistant at least 10 minutes

Permanent contact (> 480 min):

Protective gloves: type A or B; code letters: I, K; permeation-resistant at least 30 minutes

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/physical state: reddish, granular powder

Odour: characteristic
Odour threshold: no data available
Melting point/freezing point: no data available
Initial boiling point and boiling range: no data available
Flammability: no data available

according to Regulation (EC) No 1907/2006



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Lower explosive limit: not applicable

Upper explosive limit: not applicable

Flash point: not applicable

Auto-ignition temperature: no data available

pH (5 g/l H_2O): 11.5 – 12.5 (20 °C)

Kinematic viscosity: no data available
Solubility in water: completely soluble
Partition coefficient: not applicable

n-octanol/water

ir octanol, water

Vapour pressure: not applicable

Density: no data available (... °C)

Relative vapour density: not applicable Particle characteristics: not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Self-heating substances and mixtures:

Explosive substances/mixtures and products containing

explosives:

Flammable gases:

Aerosols:

Oxidising gases:

Gases under pressure:

not applicable
not applicable
not applicable

Flammable liquids: not applicable
Flammable solids: not applicable
Self-reactive substances and mixtures: not applicable
Pyrophoric liquids: not applicable
Pyrophoric solids: not applicable

Substances and mixtures, which emit flammable gases in contact with water:

Oxidising liquids:

Oxidising solids:

Organic peroxides:

Substances and mixtures corrosive to metals:

Desensitised explosives:

not applicable
not applicable
not applicable

not applicable

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9.2.2. Other safety characteristics

Electrical conductivity (5 g/l H₂O): 5500 - 7500 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

No incompatible materials known when used as intended.

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 $ATE_{mix} > 20 \text{ mg/l}$

=> no classification

Ingredients

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

Acute toxicity - oral: LD₅₀: 1152 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

No classification. [calculation method]

according to Regulation (EC) No 1907/2006



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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]

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.

Information on other hazards

Endocrine disrupting properties:

No substances are contained that have endocrine disrupting properties for humans.

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 organic ingredients.

Sodium carbonate and disodium metasilicate as inorganic substances are not subject to biodegradation.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

according to Regulation (EC) No 1907/2006



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12.5. Ergebnisse der PBT- und vPvB-Beurteilung

The substances in the mixture do not meet the PBT/vPvB criteria according to Regulation (EC) No 1907/2006, Annex XIII.

12.6. Endocrine disrupting properties

No substances are contained that have endocrine disrupting properties for non-target organisms.

12.7. 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).

From a dilution to 0.05 % the concentrate is no longer classified as a hazardous substance.

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).

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):

according to Regulation (EC) No 1907/2006



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14.4. Packing group

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. Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

14.8. Further information

Transport category according to ADR section 1.1.3.6:

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: Ε

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

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 2019/1021 on persistent organic pollutants

not applicable

REGULATION (EU) No 649/2012 concerning the export and import of hazardous chemicals

not applicable

REGULATION (EU) No 648/2004 on detergents

Enzymes: < 5 % Phosphates: < 5 %

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

according to Regulation (EC) No 1907/2006



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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

Eye Irrit. Eye irritation Skin Corr. Skin corrosion

STOT SE Specific target organ toxicity (single exposure)

H- phrases (Hazard statements)

H314 Causes severe skin burns and eye damage.

H319 Causes serious eye irritation.H335 May cause respiratory irritation.

16.2. Abbreviations and acronyms

ADN <u>A</u>ccord européen relatif au transport international des marchandises <u>d</u>angereuses par voie de

navigation 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)

BS <u>B</u>ritish <u>S</u>tandards

CAS <u>Chemical Abstracts Service</u>

CLP Regulation on Classification, Labelling and Packaging of Substances and Mixtures

[DE] National German regulations

DGUV <u>Deutsche Gesetzliche Unfallversicherung</u> (English: German statutory accident insurance)

EC <u>European Community</u>

EEC <u>European Economic Community</u>

EU European Standard
EU European Union

EWC <u>European Waste Catalogue</u>

GMBl <u>G</u>emeinsames <u>M</u>inisterial<u>bl</u>att (English: Joint Ministerial Gazette)

IATA-DGR <u>International Air Transport Association - Dangerous Goods Regulations</u>

according to Regulation (EC) No 1907/2006



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ICAO-TI Technical Instructions For The Safe Transport of Dangerous Goods by Air

IMDG-Code International Maritime Code for Dangerous Goods

LD₅₀ Median lethal dose

OECD <u>Organization for Economic Co-operation and Development</u>

PBT <u>Persistent, bioaccumulative and toxic</u>

ppm Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

RID <u>Règlement concernant le transport International ferroviaire de marchandises Dangereuses</u>

(Regulations Concerning the International Carriage of Dangerous Goods by Rail)

TRGS <u>Technische Regeln für Gefahrstoffe</u> (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>Very persistent and very bioaccumulative</u>

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 4.0 (December 2022); https://echa.europa.eu/documents
- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008; Version 4.2 (03/2021); https://echa.europa.eu/documents
- European Chemicals Agency (ECHA), Registered substances;
 - https://echa.europa.eu/information-on-chemicals/registered-substances
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory;
 https://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;
 https://www.dguv.de/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); https://webrigoletto.uba.de/rigoletto

16.4. Methods according to Article 9 of Regulation (EC) No 1272/2008 for the evaluation of information for classification purposes

Calculation method according to the criteria in Annex I 1272/2008.

Flash point according to EN ISO 2719:2002.

pH value measurement.

Material compatibility and corrosiveness in practical tests.

16.5. Training advice

Provide adequate information, instructions and training for users.

16.6. 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.