

Trade name: **Bilpron** Issue/Revision: 25.02.2019 Print date: 27.06.2019

Version: 2.0 Replaces version: 1.1

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 disinfecting 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.
	Note:	The product is intended for professional users.
1.3.	Details of the supplier of the safety data shee	et
	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]

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

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:



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

Suitable extinguishing media:	Water spray jet, alcohol resistant foam, extinguishing powder,
	carbon dioxide (CO ₂)

Unsuitable extinguishing media: Full water jet

5.2. Special hazards arising from the substance or mixture

	Hazardous combustion products:	Carbon monoxide (CO), carbon dioxide (CO ₂)
5.3.	Advice for firefighters	
	Special protective equipment:	Not necessary
	Further information:	Cool endangered containers with water spray jet.



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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 liquidbinding 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 necessaryFurther information on storage conditions:Recommended storage temperature: -10 °C - 30 °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.



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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:	Not necessary when used as intended.
Other skin protection:	Not necessary when used as intended.
Respiratory protection:	Not necessary when used as intended.
Thermal hazards:	No special protective measures necessary.

Environmental exposure controls

Not necessary

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	clear, blue liquid
Odour:	characteristic



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	Odour threshold:	no data available	
	pH (undiluted):	5.5 – 6.5	(20 °C)
	Melting point/freezing point:	no data available	
	Initial boiling point and boiling range:	no data available	
	Flash point:	not applicable	
	Evaporation rate:	no data available	
	Flammability (solid, gas):	not applicable	
	Lower explosive limit:	not applicable	
	Upper explosive limit:	not applicable	
	Vapour pressure:	no data available	(°C)
	Vapour density:	no data available	
	Relative density:	0.995 – 1.005	(20 °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:	1.3355-1.3370	(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

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

Does not decompose when used as intended.



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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 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.

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.

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).

14.1.UN number

-



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14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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

14.8. Further information

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

not applicable



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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 hazard classes and H-phrases

Hazard classes

H-phrases (Hazard statements)

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)
BGR	Berufsgenossenschaftliche <u>R</u> egeln (English: Employers' liability insurance association rules)
BS	British Standards
CLP	Regulation on <u>Classification</u> , <u>Labelling</u> and <u>P</u> ackaging of Substances and Mixtures
[DE]	National German regulations
DGUV	<u>D</u> eutsche Gesetzliche Unfallversicherung (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
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>Sy</u> stem 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	<u>International Air Transport Association - 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	e <u>I</u> nternational <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods
LGK	Lagerklasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
OECD	<u>Organization for Economic Co-operation and Development</u>
PBT	<u>P</u> ersistent, <u>b</u> ioaccumulative and <u>t</u> oxic
REACH	<u>Registration, Evaluation, Authorisation and Restriction of Chemicals</u>
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



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- UTC Coordinated Universal Time (French: Temps Universel Coordonné)
- vPvB <u>Very persistent and very 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); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>
- 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);
- <u>http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf</u>
 European Chemicals Agency (ECHA), Registered substances; <u>http://echa.europa.eu/information-on-chemicals/registered-substances</u>
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; <u>http://echa.europa.eu/information-on-chemicals/cl-inventory-database</u>
- 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); <u>http://webrigoletto.uba.de/rigoletto</u>

16.4. Training advice

Provide adequate information, instructions and training for users.

16.5. Indication of changes

A backslash 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.



Trade name: **BRS®** Activator Issue/Revision: 27.01.2021 Print date: 01.02.2021

Version: 2.0 Replaces version: 1.0

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

1.1.	Product identifier		
	Trade name:	BRS [®] Activator	
1.2.	. Relevant identified uses of the substance or mixture and uses advised against		
	Relevant identified uses:	Cleaning agent	
	Intended purpose:	BRS® Activator is a component (part II) of the Biofilm- Removing-Set (BRS®) and is used together with BRS® Remover for the main cleaning after the precleaning with BRS® PreCleaner. The BRS® Set is used for the basic cleaning of procedural water lines of medical and dental units before using Alpron or Bilpron.	
	Uses advised against:	None at intended use.	
	Note:	The product is intended for professional users.	
1.3.	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]

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

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:



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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 surfactants with non-hazardous additions 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.
Following eye contact:	Flush eyes with flowing water for several minutes holding eyelids apart. Remove contact lenses, if present and easy to do.
Following ingestion:	Rinse mouth with water. Let drink only a few sips of water (foaming product). Do not induce vomiting (risk of aspiration).

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

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media	
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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)

Trade name: BRS[®] Activator

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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 liquidbinding 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
Further information on storage conditions:	Not necessary
Storage class ([DE] TRGS 510):	LGK 12 Non-combustible liquids that are not assigned to any of the aforementioned LGK



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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:	Not necessary when used as intended.
Other skin protection:	Not necessary when used as intended.
Respiratory protection:	Not necessary when used as intended.
Thermal hazards:	No special protective measures necessary.

Environmental exposure controls

Not necessary

Trade name: **BRS® Activator** Issue/Revision: 27.01.2021 Print date: 01.02.2021



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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

	Appearance:	clear, light green liquid	
	Odour:	of tenside	
	Odour threshold:	no data available	
	pH (undiluted):	8.5 – 9.5	(20 °C)
	Melting point/freezing point:	no data available	
	Initial boiling point and boiling range:	no data available	
	Flash point:	not applicable	
	Evaporation rate:	no data available	
	Flammability (solid, gas):	not applicable	
	Lower explosive limit:	not applicable	
	Upper explosive limit:	not applicable	
	Vapour pressure:	no data available	(°C)
	Vapour density:	no data available	
	Relative density:	0.991 – 0.999	(20 °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:	no data available	(°C)
	Electrical conductivity (undiluted):	2000 – 2500 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



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

Acute toxicity - inhalation: Acute To

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

Skin corrosion/irritation

Product

No data available.

Serious eye damage/irritation

Product

No data available.

Respiratory or skin sensitisation

Product

No data available.

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No data available.

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 data available.

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).



Trade name: **BRS®** Activator Issue/Revision: 27.01.2021

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14.1.UN number

- 14.2. UN proper shipping name
- 14.3. Transport hazard class(es)
- 14.4. Packing group
- 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

14.8. Further information

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

not applicable



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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 hazard classes H-phrases

Hazard classes

_

H-phrases (Hazard statements)

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	Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)	
BS	British Standards	
CLP		
[DE]	National German regulations	
DGUV	Deutsche Gesetzliche Unfallversicherung (English: German statutory accident insurance)	
EC	<u>European Community</u>	
EEC	<u>E</u> uropean <u>E</u> conomic <u>C</u> ommunity	
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>Globally Harmonized System of Classification, Labelling and Packaging of Chemicals</u>	
GMBI	<u>G</u> emeinsames <u>M</u> inisterial <u>bl</u> att (English: Joint Ministerial Gazette)	
IATA-DGR	International <u>Air Transport Association - Dangerous 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	
LGK	Lagerklasse (English: Storage class)	
MARPOL	International Convention for the Prevention of Marine Pollution from Ships	
OECD	Organization for Economic Co-operation and Development	
PBT	<u>P</u> ersistent, <u>b</u> ioaccumulative and <u>t</u> oxic	
REACH	<u>Registration</u> , <u>Evaluation</u> , <u>Authorisation</u> and Restriction of <u>Ch</u> emicals	
RID	<u>R</u> èglement concernant le transport <u>International ferroviaire de marchandises</u> <u>Dangereuses</u> (Regulations Concerning the International Carriage of Dangerous Goods by Rail)	
TRGS UN	Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances) United Nations	



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- UTC Coordinated Universal Time (French: Temps Universel Coordonné)
- vPvB <u>Very persistent and very 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); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>
- 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);
- <u>http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf</u>
 European Chemicals Agency (ECHA), Registered substances; <u>http://echa.europa.eu/information-on-chemicals/registered-substances</u>
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; <u>http://echa.europa.eu/information-on-chemicals/cl-inventory-database</u>
- 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); <u>http://webrigoletto.uba.de/rigoletto</u>

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. 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.

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

1.1.	Product identifier	
	Trade name:	BRS [®] PreCleaner
1.2.	Relevant identified uses of the substance or n	nixture and uses advised against
	Relevant identified uses:	Cleaning agent, enzymatic
	Intended purpose:	BRS® PreCleaner is a component (part I) of the Biofilm- Removing-Set (BRS®) and is used for the precleaning before the main cleaning with BRS® Remover and BRS® Activator (or only with BRS® Remover 3). The BRS® is used for the basic cleaning of the procedural water lines in dental treatment units before the use of Alpron or Bilpron. The biofilm and other incrustations are removed thereby.
	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 shee	t
	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]

Classification	Classification procedure
Skin Corr. 1B; H314	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	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.

No further hazards known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterisation: Mixture of subst

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 %
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
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	≥ 15 - < 20

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



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Version: 2.0

Trade name: **BRS® PreCleaner** Issue/Revision: 07.01.2021

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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 (CO ₂)
	Unsuitable extinguishing media:	Full water jet
5.2.	2. Special hazards arising from the substance or mixture	
	Hazardous combustion products:	Carbon monoxide (CO), carbon dioxide (CO ₂)
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:	reddish, 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:	1.3330-1.3343	(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} > 2000 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

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

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]

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.

SECTION 12: Ecological information

12.1. Toxicity

No classification. [calculation method]



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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.

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).

14.1.UN number

UN 3253

Safety data sheet according to Regulation (EC) No 1907/2006	
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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 7	3/78 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

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

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REGULATION (EC) No 1005/2009 on substances that deplete the ozone layer not applicable



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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

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>Accord européen relatif au transport international des marchandises 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>Accord européen relatif au transport international des marchandises dangereuses par route</u> (European Agreement concerning the International Carriage of Dangerous Goods by Road)



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	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>Classification</u> , <u>Labelling</u> 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> nfallversicherung (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	Emergency Schedules (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>Globally Harmonized System of Classification, Labelling and Packaging of Chemicals</u>	
	GMBI	<u>G</u> emeinsames <u>M</u> inisterial <u>bl</u> att (English: Joint Ministerial Gazette)	
	IATA-DGR	International <u>Air</u> 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	
		International Maritime Code for Dangerous Goods	
		Median lethal dose	
	LD50 LGK	Lagerklasse (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		
		<u>Registration</u> , <u>Evaluation</u> , <u>Authorisation</u> and Restriction of <u>Ch</u> emicals <u>Règlement concernant le transport International ferroviaire de marchandises Dangereuses</u>	
	RID	(Regulations Concerning the International Carriage of Dangerous Goods by Rail)	
	TRGS	Technische <u>R</u> egeln für <u>G</u> efahr <u>s</u> toffe (English: Technical Rules for Hazardous Substances)	
	UN UTC	<u>U</u> nited <u>N</u> ations Coordinated Universal Time (French: Temps Universel Coordonné)	
	vPvB	Very persistent and very bioaccumulative	
16.3		re references and sources for data	
10.5	-	ion (EC) No 1907/2006 (REACH), Annex II	
	-	an Chemicals Agency (ECHA) – Guidance on the compilation of safety data sheets; Version 2.1	
		ary 2014); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>	
		(Hazardous substances information system of the BG BAU) – course "safety data sheet";	
		www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm	
		tion (EC) No 1272/2008 (CLP regulation)	
	 European Chemicals Agency (ECHA) – Guidance on Labelling and Packaging in accordance with 		
		tion (EC) No 1272/2008 (04/2011);	
	-	echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf	
	- European Chemicals Agency (ECHA), Registered substances;		
		echa.europa.eu/information-on-chemicals/registered-substances	
	- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory;		
		echa.europa.eu/information-on-chemicals/cl-inventory-database	
	-	e for Occupational Safety and Health of the German Social Accident Insurance (IFA):	
		database on hazardous substances and GESTIS - International limit values for chemical agents;	
		www.dguv.de/dguv/ifa/index.jsp	
		n Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and	
		ation on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to	
); <u>http://webrigoletto.uba.de/rigoletto</u>	



Trade name: **BRS®** PreCleaner

Issue/Revision: 07.01.2021 Print date: 14.01.2021 Version: 2.0 Replaces version: 1.0

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. 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.



Trade name: **BRS® Remover** Issue/Revision: 01.02.2021

Print date: 04.02.2021

Version: 2.0 Replaces version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1. Product identifier Trade name: **BRS® Remover** 1.2. Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses: **Cleaning agent** Intended purpose: BRS® Remover is a component (part II) of the Biofilm-Removing-Set (BRS®) and is used together with BRS® Activator for the main cleaning after the precleaning with BRS[®] PreCleaner. The BRS® is used for the basic cleaning of procedural water lines of medical and dental units before using Alpron or Bilpron. None at intended use. Uses advised against: The product is intended for professional users. Note: 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 +49 7725 9392-0 In-house emergency telephone number: 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]

Classification	Classification procedure
Eye Irrit. 2; H319	Calculation method

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



Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021

2.2. Label elements

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

Hazard pictograms:

Signal word:		Warning
Hazard compo for labelling:	nents	-
H-phrases:	H319	Causes serious eye irritation.
P-phrases:	P280 P305+P351+P338	Wear eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313	If eye irritation persists: Get medical advice/attention.

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	,	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Citric acid	CAS No: 77-92-9 EC No: 201-069-1 REACH Registration No: 01-2119457026-42-XXXX	Eye Irrit. 2; H319	≥ 50

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:	First aider: Pay attention to self-protection!
Following inhalation:	Move affected person into fresh air and keep still and warm. In case of continued complaints 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.

Version: 2.0 Replaces version: 1.0



Trade name: **BRS® Remover**

Issue/Revision: 01.02.2021 Print date: 04.02.2021

Version: 2.0 Replaces version: 1.0

Following ingestion: Rinse mouth with water. Let drink plenty of water. Do not induce vomiting. Consult a physician immediately.

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

Causes serious eye irritation.

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.

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. Environmental precautions

Do not discharge into drains or rivers.

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.



Trade name: **BRS® Remover**

Issue/Revision: 01.02.2021 Print date: 04.02.2021 Version: 2.0 Replaces version: 1.0

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:	Not necessary
Further information on storage conditions:	Not necessary
Storage class ([DE] TRGS 510):	LGK 11 Combustible solids that cannot be assigned to any of the above storage classes

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



Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021 Version: 2.0 Replaces version: 1.0

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) must be located near the workplace.

Personal protective equipment

Eye/face protection: Skin protection:	Safety glasses with side protection according to EN 166
Hand protection:	Protective gloves according to EN 374 are recommended <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:	Not necessary when used as intended.
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

•	information on basic physical and the	ennear properties	
	Appearance:	light blue powder	
	Odour:	characteristic	
	Odour threshold:	no data available	
	pH (80 g/l H ₂ O):	1.5 – 2.0	(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	
	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	



Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021 Version: 2.0 Replaces version: 1.0

	Auto-ignition temperature:	not applicable	
	Decomposition temperature:	no data available	
	Viscosity:	no data available	
	Explosive properties:	none	
	Oxidising properties:	none	
•	Other information		
	Refractive index nD (80 g/l H ₂ O):	1.3418 – 1.3433	(20 °C)
	Electrical conductivity (80 g/l H ₂ O):	6000 – 6500 μS/cm	(20 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

9.2.

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} > 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 mg/l => no classification

Skin corrosion/irritation

Product

No data available.

Serious eye damage/irritation

Product

Causes serious eye irritation. [calculation method]

Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021



Version: 2.0 Replaces version: 1.0

Respiratory or skin sensitisation

Product

No data available.

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No data available.

STOT-repeated exposure

Product

No data available.

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.



Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021

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: 16 03 05* organic wastes containing hazardous substances

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

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).

14.1.UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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

14.8. Further information



Trade name: **BRS® Remover** Issue/Revision: 01.02.2021

Version: 2.0 Replaces version: 1.0

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

Print date: 04.02.2021

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

not applicable

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

Eye Irrit. Eye irritation

H-phrases (Hazard statements)

H319 Causes serious eye irritation.



Trade name: BRS® Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021

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 dangereuses par route
ADI	(European Agreement concerning the International Carriage of Dangerous Goods by Road)
BGR	Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)
BS	British Standards
CAS	<u>Chemical Abstracts Service</u>
CLP	Regulation on Classification, Labelling and Packaging of Substances and Mixtures
[DE]	National German regulations
DGUV	Deutsche Gesetzliche Unfallversicherung (English: German statutory accident insurance)
EC	European Community
EEC	European Economic Community
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	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 <u>Air Transport Association - Dangerous 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
LGK	Lagerklasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
OECD	Organization for Economic Co-operation and Development
PBT	Persistent, <u>b</u> ioaccumulative and <u>t</u> oxic
REACH	<u>Registration</u> , <u>Evaluation</u> , <u>Authorisation</u> and Restriction of <u>Ch</u> emicals
RID	<u>R</u> èglement concernant le transport <u>International ferroviaire de marchandises</u> <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	United Nations
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); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>
- GISBAU (Hazardous substances information system of the BG BAU) course "safety data sheet"; <u>http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm</u>
- 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; <u>http://echa.europa.eu/information-on-chemicals/cl-inventory-database</u>
- 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; <u>http://www.dguv.de/dguv/ifa/index.jsp</u>



Trade name: BRS[®] Remover

Issue/Revision: 01.02.2021 Print date: 04.02.2021

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); <u>http://webrigoletto.uba.de/rigoletto</u>

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. 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.



Trade name: **Alpron** Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

1.1. Product identifier Trade name: Alpron 1.2. Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses: Cleaning and disinfecting agent Intended purpose: Liquid concentrate for the continuous maintenance of the water quality in procedural water lines (including instruments and tumbler filler) 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 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

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

E-mail address for the competent person responsible for the safety data sheet:

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

Poisoning information centre, Freiburg, Germany

Poison centre:

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
Aquatic Chronic 3; H412	Calculation method

+49 761 19240

doku@alpro-medical.de

(24 h / 7 d), English is spoken

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: Signal word:

Hazard components for labelling:



Trade name: **Alpron**

Issue/Revision: 08.03.2019	
Print date: 03.06.2019	

H-phrases:	H412	The concentrate is harmful to aquatic life with long lasting effects.
EUH-phrases:	EUH208	Contains polyhexamethylenebiguanidehydrochloride. The concentrate may produce an allergic reaction.
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 edetic acid, biguanide, tosylchloramide sodium, scents and flavouring substances in aqueous solution.

Chemical name	Identification numbers	Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Disodium dihydrogen- ethylenediaminetetra- acetate	CAS No: 139-33-3 EC No: 205-358-3 REACH Registration No: 01-2119486775-20-XXXX	Acute Tox. 4; H332	≥1-<5
Guanidine, N,N'''-1,3- propanediyl-bis-, N- coco alkyl derivatives	CAS No: 98246-84-5 EC No: 308-757-1	Acute Tox. 4; H302 Skin Corr. 1B; H314 Aquatic Acute 1; H400	< 0.2
Polyhexamethylene- biguanidehydro- chloride	CAS No: 1802181-67-4 (32289-58-0)	Acute Tox. 4; H302 Skin Sens. 1B; H317 STOT SE 3; H335 Eye Dam. 1; H318 Acute Tox. 2; H330 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <i>M-Factor acute: 10</i> <i>M-Factor chronic: 10</i>	< 0.2
Tosylchloramide- sodium	CAS No: 7080-50-4	Acute Tox. 4; H302 Skin Corr. 1B; H314 Resp. Sens. 1; H334 EUH031	< 0.2

Hazardous ingredients

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

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:	By way of precaution, wash skin with water and soap. In case of skin reactions, consult a physician.



Trade name: Alpron Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

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

Suitable extinguishing media:	Water spray jet, alcohol resistant foam, extinguishing powder, carbon dioxide (CO ₂)
Unsuitable extinguishing media:	Full water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:	Carbon monoxide (CO), carbon dioxide (CO ₂), nitrogen oxides (NO _x),
	hydrogen chloride (HCl), chlorine (Cl ₂) and chlorine dioxide (ClO ₂)

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.

Avoid skin and eye contact. Special danger of slipping by leaked/spilled product.

For emergency responders

Use personal protective equipment. See SECTION 8.2.

6.2. Environmental precautions

Do not discharge into drains or rivers.

6.3. Methods and material for containment and cleaning up

Containment

For large spills, dyke spilled material or otherwise contain material to ensure runoff does not reach a waterway. Cover or seal drains.

Cleaning up

Wipe up small amounts with absorbent material (e.g. cloth, fleece). Absorb large amounts with liquidbinding material (sand, diatomaceous earth, universal binder, sawdust). Collect in suitable, closed containers for disposal. Clean contaminated surfaces thoroughly.

Other information

Inappropriate containment and cleaning methods are not known.



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

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.

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
Further information on storage conditions:	Recommended storage temperature: 5 °C – 30 °C Protect from frost and light.
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



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019

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:	Safety glasses with side protection according to EN 166 are recommended
	Skin protection:	
	Hand protection:	Protective gloves according to EN 374 are recommended <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:	Not necessary when used as intended.
	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:	clear, yellowish liquid	
Odour:	of mint	
Odour threshold:	no data available	
pH (undiluted):	5.0 - 6.0	(20 °C)
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flash point:	not applicable	
Evaporation rate:	no data available	
Flammability (solid, gas):	not applicable	
Lower explosive limit:	not applicable	
Upper explosive limit:	not applicable	
Vapour pressure:	no data available	(°C)
Vapour density:	no data available	
Relative density:	1.015 – 1.025	(20 °C)
Solubility in water:	completely soluble	



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019

	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:	1.3447-1.3463	(20 °C)
	Electrical conductivity (undiluted):	13.50-14.50 mS/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} > 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 mg/l => no classification

Ingredients

Disodium dihydrogenethylene Acute toxicity - inhalation:	ediaminetetraacetate (CAS No: 139-33-3): LC₅₀: 1000 – 5000 mg/m³; species: rat; 6 h; method: OECD 403
,	ediyl-bis-, N-coco alkyl derivatives (CAS No: 98246-84-5):
Acute toxicity - oral:	LD₅0: 500 - 2000 mg/kg; species: rat



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

Polyhexamethylenebiguanidehydrochloride (CAS No: 1802181-67-4):Acute toxicity - inhalation:LC50: 1.61 mg/l; species: rat; method: OECD 403

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.

Aspiration hazard

Product

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. [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.



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

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: 16 10 01* aqueous liquid wastes containing hazardous substances

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

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).

14.1.UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group



Trade name: **Alpron** Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

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

14.8. Further information

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

not applicable

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.



Trade name: **Alpron** Issue/Revision: 08.03.2019 Print date: 03.06.2019

Version: 2.0 Replaces version: 1.1

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 Sens.	Skin sensitization
STOT SE	Specific target organ toxicity (single exposure)

H-phrases (Hazard statements)

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

EUH-phrases (Supplemental hazard information and label elements)

Contact with acids liberates toxic gas.

16.2. Abbreviations and acronyms

EUH031

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>Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)</u>
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>Labelling and Packaging of Substances and Mixtures</u>
[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
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>Harmonized System of Classification</u> , 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



Trade name: Alpron

Issue/Revision: 08.03.2019 Print date: 03.06.2019 Version: 2.0 Replaces version: 1.1

- 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 Maritime Code for Dangerous Goods LC_{50} Median lethal concentration LD₅₀ Median lethal dose LGK Lagerklasse (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 Règlement concernant le transport International ferroviaire de marchandises Dangereuses (Regulations Concerning the International Carriage of Dangerous Goods by Rail) TRGS Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances) UN United Nations
- UTC Coordinated Universal Time (French: Temps Universel Coordonné)
- vPvB <u>Very persistent and very 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); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>
 - GISBAU (Hazardous substances information system of the BG BAU) course "safety data sheet"; <u>http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm</u>
 - 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; <u>http://echa.europa.eu/information-on-chemicals/registered-substances</u>
 - 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); <u>http://webrigoletto.uba.de/rigoletto</u>

16.4. Training advice

Provide adequate information, instructions and training for users.

16.5. Indication of changes

A backslash 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.



Trade name: **BC-San 100** Issue/Revision: 08.12.2020 Print date: 12.01.2021

Version: 2.2 Replaces version: 2.1

SECTION 1: Identification of the substance/mixture and of the company/undertaking 1.1. Product identifier Trade name: BC-San 100 1.2. Relevant identified uses of the substance or mixture and uses advised against Relevant identified uses: **Disinfecting agent** Intended purpose: Solution for the virucidal final disinfection of surfaces of medical devices, such as light guides, polymerisation lamps, heads of intraoral cameras/scanners, as well as for the disinfection/processing of wipe dispenser boxes and pressure cylinders (1 - 1.5 L) of stand-alone procedural water supply systems such as the ALPRO-BCS (BottleCareSystem). None at intended use. Uses advised against: The product is intended for professional users. Note: 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]

Classification	Classification procedure
Eye Irrit. 2; H319	Calculation method
Skin Irrit. 2; H315	Calculation method
Aquatic Chronic 3; H412	Calculation method

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



Trade name: BC-San 100

Issue/Revision: 08.12.2020 Print date: 12.01.2021

2.2. Label elements

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

Hazard pictograms:

Signal word:

$\langle ! \rangle$
Warning

	•		-
Hazard components		nents	Sodium hypochlorite solution with 1 - 2 % active chlorine
	for labelling:		Source in hypochionite solution with 1 - 2 % active chionne
	H-phrases:	H315	Causes skin irritation.
		H319	Causes serious eye irritation.
		H412	Harmful to aquatic life with long lasting effects.
	P-phrases:	P280	Wear protective gloves/eye protection/face protection.
		P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove
			contact lenses, if present and easy to do. Continue rinsing.
		P337+P313	If eye irritation persists: Get medical advice/attention.

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 in aqueous solution.

Hazardous ingredients

Chemical name	Identification numbers	Classification in accordance with	Weight %
		Regulation (EC) No 1272/2008	
Sodium hypochlorite	CAS No: 7681-52-9	Met. Corr. 1; H290	≥1-<2
	EC No: 231-668-3	Skin Corr. 1B; H314	
	Index No: 017-011-00-1	STOT SE 3; H335	
	REACH Registration No:	Aquatic Acute 1; H400	
	01-2119488154-34-XXXX	Aquatic Chronic 1; H410	
		EUH031	
		M-Factor acute: 10	
		M-Factor chronic: 1	
		Specific concentration limits	
		EUH031: C ≥ 5 %	
		(further specific concentration limits:	
		see ECHA -> Registered substances)	

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

SECTION 4: First aid measures

4.1. Description of first aid measures



Trade name: BC-San 100

Issue/Revision: 08.12.2020 Print date: 12.01.2021

Version:	2.2
Replaces version:	2.1

General information:	First aider: Pay attention to self-protection!
Following inhalation:	Move affected person into fresh air and keep still and warm. In case of continued complaints 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. Consult a physician immediately.

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

Causes skin irritation. Causes serious eye irritation.

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: Hydrogen chloride (HCl), chlorine (Cl₂) and chlorine dioxide (ClO₂)

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 vapours. Provide adequate ventilation. Special danger of slipping by leaked/spilled product. 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.

6.3. Methods and material for containment and cleaning up

Containment

For large spills, dyke spilled material or otherwise contain material to ensure runoff does not reach a waterway. Cover or seal drains.



Trade name: BC-San 100

Issue/Revision: 08.12.2020 Print date: 12.01.2021

Cleaning up

Wipe up small amounts with absorbent material (e.g. cloth, fleece). Absorb large amounts with liquidbinding material (sand, diatomaceous earth, universal binder, sawdust). 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 breathing aerosols and vapours. 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 and kept upright to prevent any leakage.
Advice on common storage:	Not necessary
Further information on storage conditions:	Protect from heat and direct sunlight.
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



Trade name: BC-San 100

Issue/Revision: 08.12.2020 Print date: 12.01.2021 Version: 2.2 Replaces version: 2.1

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

	Limit values					
Country	Long term (8 hours)		Short term (15		Legal basis	Remarks
Country			minutes)			
	ррт	mg/m³	ррт	mg/m³		
Chlorine (CAS No: 7782-50-5) as decomposition product of sodium hypochlorite						
EU	-	-	0.5	1.5	2006/15/EC	-
UK	-	-	0.5	1.5	EH40	

Used abbreviations, symbols, numerals and explanations in column "Remarks"

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) 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:	Not necessary when used as intended.
Respiratory protection:	Not necessary when used as intended.
Thermal hazards:	No special protective measures necessary.
Environmental exposure controls	

Do not discharge into drains.

ALPRO MEDICAL GMBH

Trade name: **BC-San 100** Issue/Revision: 08.12.2020 Print date: 12.01.2021

Version: 2.2 Replaces version: 2.1

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

		• •	
	Appearance:	clear, yellowish liquid	
	Odour:	of chlorine	
	Odour threshold:	no data available	
	pH (undiluted):	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:	no data available	
	Flammability (solid, gas):	not applicable	
	Lower explosive limit:	not applicable	
	Upper explosive limit:	not applicable	
	Vapour pressure:	no data available	(°C)
	Vapour density:	no data available	
	Relative density:	1.015 - 1.020	(20 °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:	1.3374-1.3380	(20 °C)
	Electrical conductivity (undiluted):	35-40 mS/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 relatively stable when handled and stored as intended. A small amount of sodium hypochlorite decomposes even at room temperature with release of oxygen.

10.3. Possibility of hazardous reactions

Contact with acids liberates toxic gas.

10.4. Conditions to avoid

Heat, direct sunlight



Trade name: BC-San 100

Issue/Revision: 08.12.2020 Print date: 12.01.2021

Version: 2.2 Replaces version: 2.1

10.5. Incompatible materials

Acids, oxidants

10.6. Hazardous decomposition products

Chlorine (Cl₂), hydrogen chloride (HCl), chlorine dioxide (ClO₂)

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 mg/l
	=> no classification

Skin corrosion/irritation

Product

Causes skin irritation. [calculation method]

Serious eye damage/irritation

Product

Causes serious eye irritation. [calculation method]

Respiratory or skin sensitisation

Product

No data available.

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

Sodium hypochlorite (CAS No: 7681-52-9): May cause respiratory irritation.



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STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects. [Calculation method]

12.2. Persistence and degradability

Biodegradability:

The criteria of biodegradability are not applicable on inorganic 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 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: 16 10 03* aqueous concentrates containing hazardous substances

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).



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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).

14.1.UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

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

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

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



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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

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

Aquatic Acute	Acute aquatic hazard
Aquatic Chronic	Long-term aquatic hazard
Eye Irrit.	Eye irritation
Met. Corr.	Substance or mixture corrosive to metals
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
STOT SE	Specific target organ toxicity (single exposure)

H-phrases (Hazard statements)

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

EUH-phrases (Supplemental hazard information and label elements)

EUH031 Contact with acids liberates toxic gas.

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	Accord européen relatif au transport international des marchandises dangereuses par route
	(European Agreement concerning the International Carriage of Dangerous Goods by Road)
BGR	<u>Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)</u>
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>Classification</u> , <u>Labelling and Packaging of Substances and Mixtures</u>
[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



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EEC	<u>E</u> uropean <u>E</u> conomic <u>C</u> ommunity
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	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 <u>Air Transport Association - Dangerous G</u> oods <u>Regulations</u>
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 Maritime Code for Dangerous Goods	
LGK	Lagerklasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
PBT	<u>P</u> ersistent, <u>b</u> ioaccumulative and <u>t</u> oxic
ppm	<u>P</u> arts <u>p</u> er <u>m</u> illion
REACH	<u>Registration, Evaluation, Authorisation and Restriction of Chemicals</u>
RID	<u>R</u> èglement concernant le transport <u>International ferroviaire de marchandises D</u> angereuses
	(Regulations Concerning the International Carriage of Dangerous Goods by Rail)
TRGS	Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances)
UN	<u>U</u> nited <u>N</u> ations
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); <u>http://echa.europa.eu/documents/10162/13643/sds_en.pdf</u>
- 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; <u>http://echa.europa.eu/information-on-chemicals/registered-substances</u>
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; <u>http://echa.europa.eu/information-on-chemicals/cl-inventory-database</u>
- 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;
 <u>http://www.dguv.de/dguv/ifa/index.jsp</u>
- 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); <u>http://webrigoletto.uba.de/rigoletto</u>

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. This information is based on the latest state of our knowledge at the time of revision. In partic-



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ular, 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.