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

1.1. Product identifier

Trade name:	**BC-San 100**
UFI:	NYMU-1KYA-D006-PP7G

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).
Uses advised against:	None at intended use.
Note:	The product is intended for professional users.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier:	ALPRO MEDICAL GMBH Mooswiesenstraße 9 D-78112 St. Georgen (Germany) Telephone: +49 7725 9392-0 Telefax: +49 7725 9392-91 E-mail: info@alpro-medical.de Internet: www.alpro-medical.de
E-mail address for the competent person responsible for the safety data sheet:	doku@alpro-medical.de

1.4. Emergency telephone number

In-house emergency telephone number:	+49 7725 9392-0 Monday – Friday from 08:00 am to 04:30 pm (UTC+1); for chemical information and legal information on hazardous substances only
Poison centre:	+49 761 19240 Poisoning information centre, Freiburg, Germany (24 h / 7 d), English is spoken
National Poisons Information Service (UK):	+44 344 892 0111 National Poisons Information Service (NPIS) (24 h / 7 d), Medical Professionals Only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Classification	*Classification procedure*
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.

2.2. Label elements

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

Hazard pictograms:



Signal word: Warning

Hazard components for labelling: Sodium hypochlorite solution with 1 - 2 % active chlorine

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 (see SECTION 12.5.).

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

No further hazards known.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

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

Hazardous ingredients

Chemical name	*Identification numbers*	*Classification in accordance with Regulation (EC) No 1272/2008*	*Weight %*
Sodium hypochlorite	CAS No: 7681-52-9 EC No: 231-668-3 Index No: 017-011-00-1 REACH Registration No: 01-2119488154-34-XXXX	Met. Corr. 1; H290 Skin Corr. 1B; H314 STOT SE 3; H335 Aquatic Acute 1; H400 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)*	≥ 1 - < 2

Full text of hazard classes, H- and EUH-phrases: see SECTION 16.1.
Occupational exposure limits: see SECTION 8.1

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.
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 (CO_2)
Unsuitable extinguishing media:	Full water jet

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:	Hydrogen chloride (HCl), chlorine (Cl_2) and chlorine dioxide (ClO_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

Nicht für Notfälle geschultes Personal

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 surface and ground water.

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 liquid-binding 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. Do not mix with acids.

Advice on general occupational hygiene

When using do not eat, drink or smoke. Wash hands before breaks and at end of work. Keep away from medicines, food, feed, cosmetics and stimulants.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels:	Keep only in the original container. Keep container tightly closed and kept upright to prevent any leakage.
Advice on common storage:	Not necessary
Further information on storage conditions:	Do not store above 30 °C. Keep away from sunlight.

7.3. Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific end uses are stipulated.

Industry and sector specific guidance

[DE] TRGS 525 – Hazardous substances in medical care facilities (Section 7 Activities with disinfectants); Issue: September 2014;
Source: GMBl 2014 page 1294-1307 of 13.10.2014 [No 63]; 10.07.2015 [No 27];
www.baua.de.

[DE] DGUV rules 207-206 – Prevention of chemical risks when handling disinfectants in health service, Issue: 2016.12;
Source: www.dguv.de/publikationen

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Country	*Limit values*				*Legal basis*	*Remarks*
	Long term (8 hours)		*Short term (15 minutes)*			
	ppm	*mg/m³*	*ppm*	*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 482:2021-04; Title: Workplace exposure - Procedures for the determination of the concentration of chemical agents;
British version of EN 482:2021

BS EN 689:2018; Title: Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy;
British version of EN 689:2018

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)

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

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

8.2. Exposure controls

Appropriate engineering controls

Technical and organisational protective measures

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

Personal protective equipment

Eye/face protection: Safety glasses with side protection according to BS EN 166

Skin protection:

Hand protection: Protective gloves according to BS EN ISO 374-1 and BS EN 21420
Splash guard:
Protective gloves: type C; permeation-resistant at least 10 minutes
Permanent contact (> 480 min):
Protective gloves: type A or B; code letters: K;
permeation-resistant at least 30 minutes

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/physical state:	clear, yellowish liquid	
Odour:	of chlorine	
Odour threshold:	no data available	
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flammability (solid, gas):	no data available	
Lower explosive limit:	not applicable	
Upper explosive limit:	not applicable	
Flash point:	not applicable	
Auto-ignition temperature:	no data available	
pH (undiluted):	11.5 – 12.5	(20 °C)
Kinematic viscosity:	no data available	
Solubility in water:	completely soluble	
Partition coefficient: n-octanol/water	not applicable	
Vapour pressure:	not applicable	(… °C)
Density:	1.015 – 1.020 g/cm^3	(20 °C)
Relative vapour density:	not applicable	
Particle characteristics:	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive substances/mixtures and products containing explosives:	not applicable
Flammable gases:	not applicable
Aerosols:	not applicable
Oxidising gases:	not applicable
Gases under pressure:	not applicable
Flammable liquids:	not applicable
Flammable solids:	not applicable
Self-reactive substances and mixtures:	not applicable

Pyrophoric liquids:	not applicable
Pyrophoric solids:	not applicable
Self-heating substances and mixtures:	not applicable
Substances and mixtures, which emit flammable gases in contact with water:	not applicable
Oxidising liquids:	not applicable
Oxidising solids:	not applicable
Organic peroxides:	not applicable
Substances and mixtures corrosive to metals:	Not suitable for unalloyed metals
Desensitised explosives:	not applicable

9.2.2. Other safety characteristics

Electrical conductivity (undiluted):	37 – 42 mS/cm	(20 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when handled and stored as intended.
Develops toxic gases on contact with acid.

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

10.5. Incompatible materials

Acids, oxidants, not suitable for unalloyed metals

10.6. Hazardous decomposition products

Chlorine (Cl_2), hydrogen chloride (HCl), chlorine dioxide (ClO_2)

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.

STOT-repeated exposure

Product

No data available.

Aspirationsgefahr

Product

No data available.

Information on other hazards

Endocrine disrupting properties:

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

SECTION 12: Ecological information

12.1. Toxicity

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. Endocrine disrupting properties

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

12.7. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal of the product

Product residues must be disposed of as hazardous waste in compliance with the Directive 2008/98/EC on waste as well as national and regional regulations. Do not dispose of via the waste water. Leave product in the original container as possible. Do not mix with other waste materials.

Waste codes / waste designations according to EWC

Product residues:	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).

From a dilution to 10 % the concentrate is no longer classified as a hazardous substance.

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. Maritime transport in bulk according to IMO instruments

-

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 2019/1021 on persistent organic pollutants

not applicable

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

not applicable

REGULATION (EU) No 648/2004 on detergents

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 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	Accord européen relatif au transport international des marchandises dangereuses 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)
BS	British Standards
CAS	Chemical Abstracts Service
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	European Union
EWC	European Waste Catalogue
GMBl	Gemeinsames Ministerialblatt (English: Joint Ministerial Gazette)
IATA-DGR	International Air Transport Association - Dangerous Goods Regulations
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
LD_{50}	Median lethal dose
OECD	Organization for Economic Co-operation and Development
PBT	Persistent, bioaccumulative and toxic
ppm	Parts per million
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	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 4.0 (December 2022); https://echa.europa.eu/documents

- Regulation (EC) No 1272/2008 (CLP regulation)
- European Chemicals Agency (ECHA) – Guidance on Labelling and Packaging in accordance with Regulation (EC) No 1272/2008; Version 4.2 (03/2021); https://echa.europa.eu/documents
- European Chemicals Agency (ECHA), Registered substances; https://echa.europa.eu/information-on-chemicals/registered-substances
- European Chemicals Agency (ECHA), C&L Classification and Labelling Inventory; https://echa.europa.eu/information-on-chemicals/cl-inventory-database
- Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA): GESTIS database on hazardous substances and GESTIS - International limit values for chemical agents; https://www.dguv.de/ifa/index.jsp
- German Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and Information on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to Waters); https://webrigoletto.uba.de/rigoletto

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

Calculation method according to the criteria in Annex I 1272/2008.
Flash point according to EN ISO 2719:2002.
pH value measurement.
Material compatibility and corrosiveness in practical tests.

16.5. Training advice

Provide adequate information, instructions and training for users.

16.6. Indication of changes

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

The information given in the safety data sheet only applies to the described product in connection with its intended use. This information is based on the latest state of our knowledge at the time of revision. In particular, it describes our product under the aspect of its hazards and safety measures to be taken. It does not constitute any guarantee of product properties and quality features.

Dieses Dokument wird Ihnen zur Verfügung gestellt von:

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