according to Regulation (EC) No 1907/2006



Trade name: WL-clean Issue/Revision: 05.11.2015

Version: 1.1 Print date: 05.11.2015 Replaces version: 1.0

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

1.1 Product identifier

Trade name: **WL-clean**

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

Relevant identified uses: Cleaning agent

Intended purpose: All-purpose rinsing and cleaning solution ready for use for

> the non protein fixing inner cleaning and decontamination of hollow part instruments, e. g. dental turbines, handpieces and contra-angles, internally cooled instruments and endoscopes prior to the disinfection/ sterilisation.

Uses advised against: None at intended use.

Note: The product is intended for professional users.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier: ALPRO MEDICAL GMBH

Mooswiesenstraße 9

D-78112 St. Georgen (Germany) Telephone: +49 7725 9392-0 Telefax: +49 7725 9392-91 E-mail: alpro@alpro-medical.de Internet: www.alpro-medical.com

E-mail address for the competent person

responsible for the safety data sheet:

doku@alpro-medical.de

1.4. Emergency telephone number

In-house emergency telephone number: +49 7725 9392-0

> Monday - Friday from 08:00 am to 04:30 pm (UTC+1); for chemical information and legal information on

hazardous substances only

Poison centre: +49 761 19240

Poisoning information centre, Freiburg, Germany

(24 h / 7 d), English is spoken

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Classification	Classification procedure	
Aerosol 3; H229	Aerosol contains ≤ 1 % flammable components	
	and its heat of combustion is < 20 kJ/g	

Full text of hazard classes as well as H-phrases: see under SECTION 16.3.

Classification in accordance with Directive 1999/45/EC

see SECTION 16.1.

2.2. Label elements

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

Hazard pictograms:

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015 Version: 1.1
Print date: 05.11.2015 Replaces version: 1.0

Signal word: Warning

Hazard components

for labelling: -

H-phrases: H229 Pressurised container: May burst if heated.

P-phrases: P210 Keep away from heat, hot surfaces, sparks, open flames and other

ignition sources. No smoking.

P251 Do not pierce or burn, even after use.

P410+P412 Protect from sunlight. Do not expose to temperatures exceeding

50 °C/122 °F.

Label elements in accordance with Directive 1999/45/EC

see SECTION 16.2.

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 and propellant.

Hazardous ingredients

Chemical name	Identification numbers	Classification	Classification	Weight %
		in accordance	in accordance with	
		with Directive	Regulation (EC)	
		67/548/EEC	No 1272/2008	
Carbon dioxide	CAS No: 124-38-9	-	Press. Gas L; H280	≥ 0,5 - < 1
	EC No: 204-696-9			

Full text of code letters, hazard classes, R- and H-phrases: see SECTION 16.3.

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

No information available.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015 Version: 1.1
Print date: 05.11.2015 Replaces version: 1.0

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: 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 liquid-binding 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

Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding $50 \, ^{\circ}\text{C}/122 \, ^{\circ}\text{F}$.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015 Version: 1.1
Print date: 05.11.2015 Replaces version: 1.0

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: The official regulations regarding the storage of

pressurized containers have to be considered. Keep

container in a cool, well-ventilated place.

Advice on common storage: Not necessary

Further information on storage conditions: Recommended storage temperature: 0 °C – 25 °C

Storage class ([DE] TRGS 510): LGK 2B Aerosol dispensers and lighters

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

	Limit values						
Country	Long term	n (8 hours)		erm (15	Legal basis	Remarks	
Country				minutes)		Kemarks	
	ppm	mg/m³	ppm	mg/m³			
Carbon dioxide (CAS No: 124-38-9)							
EU	5000	9000	-	-	2006/15/EG	-	
UK	5000	9150	15000	27400	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

according to Regulation (EC) No 1907/2006



Trade name: WL-clean Issue/Revision: 05.11.2015

Version: 1.1 Print date: 05.11.2015 Replaces version: 1.0

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

clear, colourless aerosol Appearance:

Odour: characteristic Odour threshold: no data available

6.5 - 7.5pH (undiluted): (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

Vapour pressure: no data available (... °C)

not applicable

no data available Vapour density:

Relative density: 0.995 - 1.005(20°C)

completely soluble Solubility in water: Partition coefficient: not applicable

n-octanol/water

Upper explosive limit:

Auto-ignition temperature: not applicable Decomposition temperature: no data available no data available Viscosity:

Explosive properties: none Oxidising properties: none

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015 Version: 1.1
Print date: 05.11.2015 Replaces version: 1.0

9.2. Other information

Refractive index nD: 1.3342-1.3359 (20 °C) Electrical conductivity (undiluted): $1700-1900 \,\mu\text{S/cm}$ (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

Keep away from heat.

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 $ATE_{mix} > 2000 \text{ mg/kg}$

=> no classification

Acute toxicity - dermal: Acute Toxicity Estimate $ATE_{mix} > 2000 \text{ mg/kg}$

=> no classification

Acute toxicity - inhalation: Acute Toxicity Estimate $ATE_{mix} > 20 \text{ mg/l}$

=> 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]

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Version: 1.1 Replaces version: 1.0

Germ cell mutagenicity

Product

Print date: 05.11.2015

No data available.

Carcinogenicity

Product

No classification. [calculation method]

Reproductive toxicity

Product

No data available.

STOT-single exposure

Product

No classification. [calculation method]

STOT-repeated exposure

Product

No classification. [calculation method]

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.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015Version: 1.1Print date: 05.11.2015Replaces version: 1.0

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 05 05 gases in pressure containers other than those mentioned

in 16 05 04

Disposal of the packaging

Waste codes / waste designations according to EWC

Contaminated packaging: 15 01 04 metallic packaging

Recommendation

Contaminated pressurized containers must be emptied optimally and can be recycled.

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 1950

14.2.UN proper shipping name

ADR/RID/ADN

AEROSOLS, asphyxiant

IMDG-Code

AEROSOLS

ICAO-TI/IATA-DGR

Aerosols, non-flammable

14.3. Transport hazard class(es)

Class: 2.2

Subsidiary risk(s):

14.4. Packing group

_

14.5. Environmental hazards

ADR/RID/ADN

Environmentally Hazardous: No

IMDG-Code

Marine Pollutant: No

14.6. Special precautions for user

Not necessary.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean** Issue/Revision: 05.11.2015

Issue/Revision: 05.11.2015Version: 1.1Print date: 05.11.2015Replaces version: 1.0

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

Not applicable for product as supplied.

14.8. Further information

Transport category according to ADR section 1.1.3.6: 3

Maximum total quantity per transport unit

according to ADR section 1.1.3.6: 1000 L

Limited quantity (Maximum quantity per inner

packaging) according to ADR/RID/ADN/IMDG-Code: 1 L Classification code according to ADR/RID/ADN: 5A

Hazard identification number according to

ADR/RID: -

Tunnel restriction code according to ADR/RID: E

Segregation group according to IMDG-Code

section 5.4.1.5.11.1: -

EmS codes: F-D, S-U

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

according to Regulation (EC) No 1907/2006



Trade name: WL-clean Issue/Revision: 05.11.2015

Version: 1.1 Print date: 05.11.2015 Replaces version: 1.0

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. Classification in accordance with Directive 1999/45/EC

Note: This is the previous classification; products with this classification can still be in the supply chain or on the market and are allowed to be sold until 01.06.2017.

No classification necessary according to Directive 1999/45/EC.

General hints: The pressurized container may burst in case of heating above 50 °C.

16.2. Label elements in accordance with Directive 1999/45/EC

Note: This is the previous labelling; products with this labelling can still be in the supply chain or on the market and are allowed to be sold until 01.06.2017.

Danger symbols:

Indications of danger:

Hazard components

for labelling: R-phrases:

S-phrases: S23 Do not breathe aerosol.

Special labelling (Directive 94/1/EC for adaption of the aerosol directive 75/324/EEC):

Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50° C. Do not pierce or burn, even after use.

16.3. Full text of code letters, hazard classes, R- and H-phrases

Code letters and categories of danger

Hazard classes

Aerosol Aerosol

Press. Gas L Gases under pressure (Liquefied gas)

R-phrases (Indications concerning special risks)

H-phrases (Hazard statements)

H229 Pressurised container: May burst if heated.

H280 Contains gas under pressure; may explode if heated.

16.4. 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)

BGR Berufsgenossenschaftliche Regeln (English: Employers' liability insurance association rules)

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 05.11.2015

Print date: 05.11.2015

Replaces version: 1.0

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 <u>European Community</u>

EEC <u>European Economic Community</u>

EmS <u>Em</u>ergency <u>S</u>chedules (Emergency response procedures for ships carrying dangerous goods)

EN European Standard EU European Union

EWC <u>European Waste Catalogue</u>

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 Air 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

IMDG-Code International Maritime Code for Dangerous Goods

LGK <u>Lagerklasse</u> (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>Persistent, bioaccumulative and toxic</u>

ppm <u>Parts per million</u>

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

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

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

TRGS <u>Technische Regeln für Gefahrstoffe</u> (English: Technical Rules for Hazardous Substances)

UN United Nations

UTC Coordinated Universal Time (French: Temps Universel Coordonné)

vPvB <u>Very persistent and very bioaccumulative</u>

16.5. Key literature references and sources for data

- Regulation (EC) No 1907/2006 (REACH), Annex II
- European Chemicals Agency (ECHA) Guidance on the compilation of safety data sheets; Version 2.1 (February 2014); http://echa.europa.eu/documents/10162/13643/sds_en.pdf
- GISBAU (Hazardous substances information system of the BG BAU) course "safety data sheet"; http://www.bgbau.de/gisbau/SDB/lehrgang/lehrgang.htm
- Regulation (EC) No 1272/2008 (CLP regulation)
- 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; http://echa.europa.eu/information-on-chemicals/cl-inventory-database
- Institute for Occupational Safety and Health of the German Social Accident Insurance (IFA):
 GESTIS database on hazardous substances and GESTIS International limit values for chemical agents;
 http://www.dguv.de/dguv/ifa/index.jsp
- German Environmental Agency (Umweltbundesamt), Section IV 2.4: Office of Documentation and Information on Substances Hazardous to Waters RIGOLETTO (catalogue of Substances Hazardous to Waters); http://webrigoletto.uba.de/rigoletto

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



Trade name: **WL-clean** Issue/Revision: 05.11.2015 Print date: 05.11.2015

Version: 1.1 Replaces version: 1.0

16.6. Training advice

Provide adequate information, instructions and training for users.

16.7. 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 apply to the described product in connection with its intended use. These information are based on the latest state of our knowledge at the time of revision. In particular, they describe our product under the aspect of its hazards and safety measures to be taken. They do not constitute any guarantee of product properties and quality features.