according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

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

1.1. Product identifier

Trade name: WL-clean

UFI: G0WU-XJFV-M000-4CYC

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

Relevant identified uses: Cleaning agent

Intended purpose: Solution ready for use for the non protein fixing cleaning

(internal and external surfaces) prior to disinfection/ sterilization of medical and dental hollow part instruments such as turbines, hand pieces and contra-angles, internally

cooled instruments and endoscopes.

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
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 16.1.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

2.2. Label elements

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

Hazard pictograms: -

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.

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 have no endocrine disrupting properties according to Regulation (EC) No 1907/2006, Annex XIV (see SECTION 11 and SECTION 12.6.).

The substances in the mixture are below the declaration limit for substances on the list of substances of very high concern 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 propylene glycol, parabens, biguanides and complexing

agents in aqueous solution and propellant.

Hazardous ingredients

Chemical name		Classification in accordance with Regulation (EC) No 1272/2008	Weight %
Carbon dioxide	CAS No: 124-38-9 EC No: 204-696-9	Press. Gas L; H280	≥ 1 - < 2.5

Full text of hazard classes and H-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: 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.

according to Regulation (EC) No 1907/2006



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

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.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

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 $50 \, ^{\circ}\text{C}/122 \, ^{\circ}\text{F}$.

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: 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.

Do not store above 50 °C.

7.3. Specific end use(s)

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

Industry and sector specific guidance

[DE] TRGS 525 – Hazardous substances in medical care facilities (Section 7 Activities with disinfectants); Issue: September 2014;

Source: GMBI 2014 page 1294-1307 of 13.10.2014 [No 63]; 10.07.2015 [No 27]; www.baua.de

[DE] DGUV rules 207-206 – Prevention of chemical risks when handling disinfectants in health

service, Issue: 2016.12;

Source: www.dguv.de/publikationen

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Limit values						
Country	Long term (8 hours)		Short term		Legal	Remarks
Country				(15 minutes)		
	ppm	mg/m³	ррт	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.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

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

No special protective measures necessary.

Personal protective equipment

Eye/face protection: Not necessary when used as intended.

Skin protection:

Hand protection:

Other skin protection:

Not necessary when used as intended.

Not necessary when used as intended.

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/physical state: clear, colourless aerosol

Odour: characteristic
Odour threshold: no data available
Melting point/freezing point: no data available
Initial boiling point and boiling range: no data available
Flammability: not applicable
Lower explosive limit: not applicable
Upper explosive limit: not applicable
Flash point: not applicable

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

Auto-ignition temperature: no data available

pH (undiluted): 5.3 – 5.8 (20 °C)

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

n-octanol/water

Vapour pressure: no data available (... $^{\circ}$ C) Density: 0.993 – 1.008 g/cm³ (20 $^{\circ}$ C)

Relative vapour density: no data available 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

not applicable

Substances and mixtures, which emit flammable gases

Self-heating substances and mixtures:

in contact with water:

Oxidising liquids:

Oxidising solids:

Organic peroxides:

Substances and mixtures, which emit harmable gases

not applicable

not applicable

not applicable

not applicable

not applicable

Desensitised explosives: not applicable

9.2.2. Other safety characteristics

Electrical conductivity (undiluted): 1600 – 1800 μS/cm (20 °C)

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions when handled and stored as intended.

according to Regulation (EC) No 1907/2006



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]

Germ cell mutagenicity

Product

No data available.

Carcinogenicity

Product

No data available.

Reproductive toxicity

Product

No data available.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

STOT-single exposure

Product

No classification. [calculation method]

STOT-repeated exposure

Product

No data available.

Aspiration hazard

Product

No data available.

Information on other hazards

Endocrine disrupting properties:

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

SECTION 12: Ecological information

12.1. Toxicity

No classification. [calculation method]

12.2. Persistence and degradability

Biodegradability:

The product is biodegradable according to OECD criteria. The statement has been derived from the properties of the 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 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.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

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.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

14.8. Further information

Transport category according to ADR section 1.1.3.6: 3

Maximum total quantity per transport unit

according to ADR section 1.1.3.6: 1000 L

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

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

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

EDTA: < 5 %

Disinfectants

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)

VOC content: < 2 %

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.

according to Regulation (EC) No 1907/2006



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

SECTION 16: Other information

16.1. Full text of hazard classes and H-phrases

Hazard classes

Aerosol Aerosol

Press. Gas L Gases under pressure (Liquefied gas)

H-phrases (Hazard statements)

H229 Pressurised container: May burst if heated.

H280 Contains gas under pressure; may explode if heated.

16.2. Abbreviations and acronyms

ADN	A	4	marchandises dangereuses par voie de
Δ1 1IXI	Accord allronden relatit a	III Tranchort International dec	marchandicos dangorolisos nar volo do

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 <u>British Standards</u>

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 <u>European Community</u>

EEC <u>European Economic Community</u>

EU European Standard
EU European Union

EWC <u>European Waste Catalogue</u>

GMBI <u>Gemeinsames Ministerial blatt</u> (English: Joint Ministerial Gazette)

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

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)

OECD Organization for Economic Co-operation and Development

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

ppm Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

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

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

TRGS Technische Regeln für Gefahrstoffe (English: Technical Rules for Hazardous Substances)

UN United Nations

UTC Coordinated Universal Time (French: Temps Universel Coordonné)

VOC Volatile Organic Compounds

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

16.3. Key literature references and sources for data

Regulation (EC) No 1907/2006 (REACH), Annex II

- European Chemicals Agency (ECHA) – Guidance on the compilation of safety data sheets; Version 4.0 (December 2022); https://echa.europa.eu/documents

- Regulation (EC) No 1272/2008 (CLP regulation)

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



Trade name: **WL-clean**Issue/Revision: 18.04.2023

Version: 3.0

Replaces version: 2.2

- 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.