## according to Regulation (EC) No 1907/2006



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## 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: 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: 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 16.1.

#### 2.2. Label elements

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

Hazard pictograms: -

Signal word: Warning

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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.

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		Classification in accordance with Regulation (EC) No 1272/2008	Weight %
	CAS No: 124-38-9 EC No: 204-696-9	Press. Gas L; H280	≥ 0,5 - < 1

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: 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.

## **SECTION 5: Firefighting measures**

## 5.1. Extinguishing media

Suitable extinguishing media: Water spray jet, alcohol resistant foam, extinguishing powder,

carbon dioxide (CO<sub>2</sub>)

Unsuitable extinguishing media: Full water jet

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#### 5.2. Special hazards arising from the substance or mixture

Hazardous combustion products: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>)

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

### 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.

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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: GMBl 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 (8 hours)		Short term (15 minutes)		Legal basis	Remarks			
	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

### 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.

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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: clear, colourless aerosol

Odour: characteristic
Odour threshold: no data available

pH (undiluted): 4.5 – 5.5 (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: not applicable

n-octanol/water

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: 1.3342-1.3360 (20 °C) Electrical conductivity (undiluted):  $1600-1800 \mu S/cm$  (20 °C)

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## **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<sub>mix</sub> > 2000 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.

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## 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

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.

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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. 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

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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

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.

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## **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 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 <u>Accord européen relatif au transport international des marchandises dangereuses par route</u>

(European Agreement concerning the International Carriage of Dangerous Goods by Road)

BGR <u>Berufsgenossenschaftliche Regeln</u> (English: Employers' liability insurance association rules)

BS <u>British Standards</u>

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>Emergency Schedules (Emergency response procedures for ships carrying dangerous goods)</u>

EN European Standard
EU European Union

EWC European Waste Catalogue

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 Parts per million

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals

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

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

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

UN United Nations

UTC Coordinated Universal Time (French: Temps Universel Coordonné)

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

## 16.3. Key literature references and sources for data

- Regulation (EC) No 1907/2006 (REACH), Annex II
- European Chemicals Agency (ECHA) Guidance on the compilation of safety data sheets; Version 2.1 (February 2014); <a href="http://echa.europa.eu/documents/10162/13643/sds">http://echa.europa.eu/documents/10162/13643/sds</a> en.pdf

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- 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); <a href="http://webrigoletto.uba.de/rigoletto">http://webrigoletto.uba.de/rigoletto</a>

#### 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.