

Safety data sheet

according to Regulation (EC) No 1907/2006



Trade name: **AlproSept-HDE gel**

Issue/Revision: 07.10.2019

Print date: 07.10.2019

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: **AlproSept-HDE gel**

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

Relevant identified uses: Disinfecting agent for hands and skin

Intended purpose: Hygienic hand disinfection as well as skin disinfection before carrying out ordinary injections and punctures of peripheral vessels.

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]

<i>Classification</i>	<i>Classification procedure</i>
Flam. Liq. 2; H225	On basis of test data (Flash point)
Eye Irrit. 2; H319	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:



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Signal word:		Danger
Hazard components for labelling:		-
H-phrases:	H225 H319	Highly flammable liquid and vapour. Causes serious eye irritation.
P-phrases:	P210 P233 P280 P305+P351+P338 P337+P313	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. 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. 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 Regulation (EC) No 1272/2008	Weight %
Ethanol	CAS No: 64-17-5 EC No: 200-578-6 Index No: 603-002-00-5 REACH Registration No: 01-2119457610-43-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	≥ 50 - < 70
Propan-2-ol	CAS No: 67-63-0 EC No: 200-661-7 Index No: 603-117-00-0 REACH Registration No: 01-2119457558-25-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	≥ 5 - < 15

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:	No special measures necessary.

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- 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 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 eye contact. Do not breathe vapours. Remove all sources of ignition. 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.

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.

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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 eyes. Avoid breathing aerosols and vapours. Keep away from sources of ignition. Take precautionary measures against static discharges. Provide adequate ventilation. 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: Not necessary

Storage class ([DE] TRGS 510): LGK 3 Flammable liquids

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

Country	Limit values				Legal basis	Remarks
	Long term (8 hours)		Short term (15 minutes)			
	ppm	mg/m ³	ppm	mg/m ³		
Ethanol (CAS No: 64-17-5)						
EU						no limit value specified
UK	1000	1920	-	-	EH40	

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Propan-2-ol (CAS No: 67-63-0)						
EU						no limit value specified
UK	400	999	500	1250	EH40	

Used abbreviations, symbols, numerals and explanations in column „Remarks“

Biological limit values

Country	Parameter	Limit value	Test material	Sampling time	Legal basis
Propan-2-ol (CAS No: 67-63-0)					
Germany	Acetone	25 mg/l	Whole blood	End of exposition, resp. end of shift	TRGS 903
	Acetone	25 mg/l	Urine	End of exposition, resp. end of shift	TRGS 903

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: 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

Do not discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: clear, colourless viscous liquid

Odour: alcoholic

Odour threshold: no data available

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pH (10 g/l H ₂ O):	6.5 – 7.5	(20 °C)
Melting point/freezing point:	no data available	
Initial boiling point and boiling range:	no data available	
Flash point:	20 °C	(EN ISO 2719:2002)
Evaporation rate:	no data available	
Flammability (solid, gas):	not applicable	
Lower explosive limit:	Ethanol: 3 vol% Propan-2-ol: 2 vol%	
Upper explosive limit:	Ethanol: 15 vol% Propan-2-ol: 13 vol%	
Vapour pressure:	no data available	(... °C)
Vapour density:	no data available	
Relative density:	0.85 – 0.88	(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:	The product is not explosive. However, formation of explosive vapour/air mixtures is possible.	
Oxidising properties:	none	

9.2. Other information

Refractive index n _D :	1.3638-1.3723	(20 °C)
Electrical conductivity (undiluted):	40 - 100 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

Vapours may form explosive mixtures with air.

10.4. Conditions to avoid

Keep away from heat and sources of ignition.

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 data available.

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

Propan-2-ol (CAS No: 67-63-0):
May cause drowsiness or dizziness.

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 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 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 04* other organic solvents, washing liquids and mother liquors

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

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 1987

14.2. UN proper shipping name

ADR/RID/ADN

ALCOHOLS, N.O.S. (Ethanol, Isopropanol)

IMDG-Code/ICAO-TI/IATA-DGR

ALCOHOLS, N.O.S. (Ethanol, Isopropanol)

14.3. Transport hazard class(es)

Class: 3

Subsidiary risk(s): -

14.4. Packing group

II

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: 2

Maximum total quantity per transport unit according to ADR section 1.1.3.6: 333 L

Limited quantity (Maximum quantity per inner packaging) according to ADR/RID/ADN/IMDG-Code: 1 L

Classification code according to ADR/RID/ADN: F1

Hazard identification number according to ADR/RID: 33

Tunnel restriction code according to ADR/RID: D/E

Segregation group according to IMDG-Code section 5.4.1.5.11.1: -

EmS codes: F-E, S-D

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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

<i>Hazard category</i>	<i>Qualifying quantity (tonnes) (lower-tier establishment)</i>	<i>Qualifying quantity (tonnes) (upper-tier establishment)</i>
P5c FLAMMABLE LIQUIDS	5.000	50.000

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

Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquid
STOT SE	Specific target organ toxicity (single exposure)

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H-phrases (Hazard statements)

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.

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	<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>C</u> lassification, <u>L</u> abelling 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> 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
EmS	<u>E</u> mergency <u>S</u> chedules (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>G</u> lobally <u>H</u> armonized <u>S</u> ystem 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>I</u> nternational <u>A</u> ir <u>T</u> ransport <u>A</u> ssociation - <u>D</u> angerous <u>G</u> oods 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	<u>I</u> nternational <u>M</u> aritime Code for <u>D</u> angerous <u>G</u> oods
LGK	<u>L</u> ager <u>k</u> lasse (English: Storage class)
MARPOL	International Convention for the Prevention of Marine Pollution from Ships
N.O.S.	Not otherwise specified
OECD	<u>O</u> rganization for <u>E</u> conomic <u>C</u> o-operation and <u>D</u> evelopment
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>R</u> egistration, <u>E</u> valuation, <u>A</u> uthorisation and Restriction of <u>C</u> hemicals
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
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); 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)

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- 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>

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.
