

SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) Article 31, Annex II as amended

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE **COMPANY/UNDERTAKING**

1.1 **Product identifier**

actisolve [®] alcosept
6E0X-M82A-J00X-3G70
Mixture
Surface disinfectant

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

Identified uses:

actisolve® alcosept is an aldehyde-free, ready-to-use surface disinfectant based on ethanol and quaternary ammonium compounds for the rapid disinfection and cleaning of surfaces of non-invasive medical devices such as operating tables. Uses advised against: Do not use for purposes other than those prescribed. Recommended restrictions on For professional use only.

use:

1.3 Details of the supplier of the safety data sheet

	Manufacturer	EU only representative
Address:	United Disinfectant Manufacturers AG Allmendstrasse 21 8320 Fehraltorf Switzerland	United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein
Telephone:	+41 (0)55 511 03 33	
Email:	info@udm.swiss	info@udm.li
Website:	www.udm.swiss	www.udm.li
	Downstream user/importer/distributor	r
Address:	Downstream user/importer/distributor United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein	·
Address: Telephone:	United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz	·
	United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz	<u>, </u>

Person responsible for preparing the SDS

Lee Moi Wong | Research & Development | Chief Research Officer (CRO) Telephone: +41 (0)55 511 03 33 Email: ra@udm.swiss

1.4 Emergency telephone number

Emergency telephone number: +386 41 635 500 * Please check the above numbers regularly as they might be subject to change.



SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Hazard type	Hazard category	Hazard statement code(s)	Classification procedure
Physical hazard	Flam. Liq. 3	H226	On basis of test data.
Health hazard	Eye Dam. 1	H318	Harmonised (legal) classification.
Health hazard	STOT SE 3	H336	Harmonised (legal) classification.

The full text for all H-statements is displayed in section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms:

	<u> </u>	
	GHS02	GHS05 GHS07
Signal word:	Danger	
Hazard statements:	H226	Flammable liquid and vapour.
	H318	Causes serious eye damage.
	H336	May cause drowsiness or dizziness.
Precautionary statements:	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P261	Avoid breathing fume/mist/vapours/spray.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P305 + P351 +	IF IN EYES: Rinse cautiously with water for several minutes.
	P338	Remove contact lenses, if present and easy to do. Continue rinsing.
	P501	Dispose of contents/container in accordance with local and national regulations.
Supplemental information:	Not applicable.	
Other hazards		
PBT or vPvB properties:	persistent, bioa	mixture contains no components considered to be either ccumulative and toxic (PBT), or very persistent and very e (vPvB) at levels of 0.1% or higher.
Endocrine disrupting properties:	endocrine disru	mixture does not contain components considered to have pting properties according to REACH Article 57(f) or Commission ulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

2.3

Classification according to Regulation (EC) No 1272/2008

at levels of 0.1% or higher.



Substance name	Identification	Classification	SCL, M-factor, ATE	Concentration
Propan-1-ol	CAS no.: 71-23-8 EC no.: 200-746-9 Index no.: 603-003-00-0 REACH no.: 01-2119486761-29-0000	Eye Dam. 1, H318 Flam. Liq. 2, H225 STOT SE 3, H336	No data available.	50% - 100%

The full text for all H-statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician. No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. When it is suspected, that there may still be harmful vapours/fumes present in the air, respiratory protection (mask; self contained breathing apparatus) must be used. Wash contaminated clothing with water before removing or use gloves. After inhalation: Remove patient to fresh air - move out of dangerous area. In case of unconsciousness bring patient into stable side position and seek medical attention. If breathing is irregular or respiratory arrest occurs provide artificial respiration. Keep at rest in a position comfortable for breathing. Seek medical help immediately. After contact with skin: Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. Immediately obtain professional medical help. After contact with eyes: Immediately flush eyes with running water, keeping eyelids apart. After 5 minutes of rinsing, remove contact lenses, if present, and continue rinsing. Consult a physician immediately. Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything After ingestion: by mouth to an unconscious person. Immediately consult a doctor. Show the physician the safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more detailed information on health effects and symptoms.

4.3 Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide. Dry chemical powder. Water spray. Alcohol resistant foam. Unsuitable extinguishing media: Full water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	In case of a fire toxic gases can be generated; do not inhale gases/smoke.
Hazardous combustion products:	No data available.



5.3 Advice for firefighters

Special protective equipment for firefighters:

Additional information:

Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (BS EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (BS EN 137).

In case of fire or heating do not breathe fumes/vapours. No action shall be taken involving any personal risk or without suitable training. Prolonged heating can cause an explosion. Vapours can form explosive mixtures with air. Cool containers at risk with water spray. If possible remove containers from endangered area. Contaminated firefighting water and fire residues must be disposed of in accordance with the local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:	Use personal protective equipment (section 8). Ensure adequate ventilation. Keep away from sources of ignition and/or heat; No smoking. No action shall be taken involving any personal risk or without suitable training. Prevent access to unprotected personnel. Evacuate the danger zone. Do not breathe vapour or mist. Avoid contact with skin, eyes and clothing.
Advice for emergency responders:	Use personal protective equipment.

6.2 Environmental precautions

Do not allow to enter drains or waterways. Prevent product from getting into subsoil/soil.

6.3 Methods and material for containment and cleaning up

Stem the spill if this does not pose risks. Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Use only explosion-proof instruments and equipment. Use spark-proof tools. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. Clean contaminated area with plenty of water.

6.4 Reference to other sections

See also sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

General advice: Use general or local exhaust ventilation to prevent inhaling vapours and aerosols. Do not discharge into drains, surface water and soil. After use immediately close container tightly. Ensure adequate ventilation. Keep away from sources of ignition - no smoking. Instructions for protection against Use spark-proof tools. Take precautionary measures against static discharges. fire and explosion: Vapours are heavier than air and spread along the floor. They form explosive mixtures with air. Advice on general occupational Use good personal hygiene practices – wash hands at breaks and when done hygiene: working with material. Do not eat, drink or smoke while working. Do not breathe vapours/mist. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see section 8.

7.2 Conditions for safe storage, including any incompatibilities



Requirements for storage room and containers:	Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers.
Further information about storage conditions:	Keep in a cool, dry and well ventilated place. Protect from open fire, heat and direct sunlight. Keep away from food, drink and animal feeding stuffs. Keep away from oxidising substances. Keep away from sources of ignition - no smoking. Store only in original container.
Stocking with different products:	Store separately from beverages, food and feed. Store separately from strong acids, bases and oxidation agents.

7.3 Specific end use(s)

See identified uses in section 1.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

Please refer to the latest edition of the appropriate source text and consult an industrial hygienist or similar professional, or local agencies, for further information.

Biological limit values

No biological exposure limits noted for the ingredient(s).

DNEL values

Substance name	Pattern of exposure	Route of exposure	Limit value
Propan-1-ol CAS no.:71-23-8	Worker (short term, systemic effects)	Inhalation	1723 mg/m³
	Worker (long term, systemic effects)	Inhalation	268 mg/m ³
	Consumer (short term, systemic effects)	Inhalation	1036 mg/m ³
	Consumer (long term, systemic effects)	Inhalation	80 mg/m ³
	Worker (long term, systemic effects)	Dermal	136 mg/kg bw/day
	Consumer (long term, systemic effects)	Dermal	81 mg/kg bw/day
	Consumer (long term, systemic effects)	Oral	61 mg/kg bw/day
PNEC values			
Substance name	Route of exposure	Limit value	
Propan-1-ol CAS no.:71-23-8	Fresh water	6.83 mg/L	
	Marine water	683 µg/L	
	Intermittent release (fresh water)	10 mg/L	
	Sewage treatment plant	96 mg/L	
	Sediment (fresh water)	27.5 mg/kg dw	
	Sediment (marine water)	2.75 mg/kg dw	

1.49 mg/kg dw

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Soil

Individual protection measures	
Eye/face protection:	Wear protective glasses during use.
Hand protection:	Short-term contact: Gloves with Protection Index of at least Class 2 (Norm EN 374, permeation time > 30 min) for substances of Class A. Long-term contact: Gloves with Protection Index of at least Class 6 (Norm EN 374, permeation time > 480 min) for substances of Class A. (Class A: primary alcohols).
Body protection:	Not required during normal use.
Respiratory protection:	Avoid aerosol formation. Use respiratory protection if aerosol is formed.



Thermal hazards:
Hygiene measures:

No data available.

Use good personal hygiene practices - wash hands at breaks and when done working with material. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols.

Environmental exposure controls

Observe the usual precautions for handling chemicals.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state:	Liquid
Form:	Clear, non-viscous liquid
Colour:	Colourless
Odour:	Of alcohol
Melting point:	No data available.
Freezing point:	No data available.
Boiling point or initial boiling point and boiling range:	No data available.
Flammability:	The product is flammable.
Lower explosion limit:	No data available.
Upper explosion limit:	No data available.
Flash point:	31 °C
Auto-ignition temperature:	Not self-igniting.
Decomposition temperature:	Not applicable.
pH-value (undiluted product):	6.5 - 7.5
pH-value (diluted product):	Not applicable (ready-to-use solution).
Kinematic viscosity:	No data available.
Solubility:	No data available.
Partition coefficient n- octanol/water:	Not applicable.
Vapour pressure at 50 °C:	No data available.
Density:	No data available.
Relative density:	0.92
Relative vapour density at 20 °C:	No data available.
Other information	
Oxidising properties:	Not oxidising.

9.2

Oxidising properties:	Not oxidising.
Explosive properties:	Vapours can form explosive mixtures with air.
Evaporation rate:	No data available.
Miscibility:	Completely miscible with water.
Other information:	No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture is not reactive.



10.2 Chemical stability

Stable at normal temperatures and pressure at least up to the expiry date printed on the container. Contact with open flame may cause ignition.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Avoid heat, flames, sparks and other sources of ignition. Containers may rupture or explode if exposed to intense heat. Avoid conditions beyond those mentioned in section 7.

10.5 Incompatible materials

Avoid contact with materials sensitive to alcohols.

10.6 Hazardous decomposition products

No dangerous decomposition products occur under normal storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Inhalation:	Information on effects are given below.
Skin contact:	Information on effects are given below.
Eye contact:	Information on effects are given below.
Ingestion:	Information on effects are given below.
Acute toxicity	
Mixture:	ATEmix: LD50 (rat, ingestion) > 5000 mg/kg
Component:	No data available.
Skin corrosion/irritation	
Mixture:	No irritation is expected. Repeated exposure may cause skin dryness or cracking.
Component:	No data available.
Serious eye damage/irritation	
Mixture:	Causes serious eye damage.
Component:	No data available.
Respiratory or skin sensitization	
Mixture:	The product is not classified as sensitising.
Component:	No data available.
Germ cell mutagenicity	
Mixture:	Not a mutagen. Does not contain ingredients with known mutagenic properties.
Component:	No data available.
Carcinogenicity	
Mixture:	Does not contain ingredients with known carcinogenic properties.
Component:	No data available.
Reproductive toxicity	
Mixture:	This product contains no ingredients with known reproductive toxicity effects.
Component:	No data available.



STOT-single exposure	
Mixture:	This product exhibits no known STOT-single exposure.
Component:	No data available.
STOT-repeated expos	ure
Mixture:	This product exhibits no known STOT-repeated exposure.
Component:	No data available.
Aspiration hazard	
Mixture:	This product exhibits no known aspiration hazard.
Component:	No data available.
Information on oth	ner hazards
Endocrine disrupting	properties
Mixture:	The substance/mixture does not contain components considered to have

endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
at levels of 0.1% or higher.
No data available.
No data available.
No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

11.2

The release of amounts present in our packaging is not expected to have any ecotoxic effects. The release of several packages of this product can have temporary and localized toxic effects on aquatic and terrestrial organisms. This product is not expected to negatively affect the function of sewage treatment plants. There is no data available from ecotoxicological tests regarding the entire product. The ecotoxicological risk has been estimated based on available data on product ingredients and concentrations, where available.

12.2 Persistence and degradability

The product ingredients possess good biodegradation properties. The surfactants included in the product comply with the requirements for the biological decomposition of Regulation (EC) No. 648/2004 on detergents. Based on available data, the biodegradability in sewage treatment plants can be categorized as high.

Substance name	Biodegradation	Basis	Remark
Propan-1-ol	75%	20 D	Readily biodegradable.

12.3	Bioaccumulative potential		
	Mixture:	Based on available data, no product ingredient is expected to exhibit bioaccumulative potential.	
	Component:	No data available.	
12.4	Mobility in soil		
	Mixture:	The product is not expected to be mobile over long distances because all product ingredients possess good biodegradability. Surface tension and absorption / desorption kinetics are not relevant to the product.	
	Component:	No data available.	



12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

The product contains no ingredients with ozone depletion potential or global warming potential. The product contains no heavy metals or their compounds as defined in 2006/11/EG. The product contains no absorbable organic halogens (AOX). The product contains volatile organic compounds (VOC).

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal methods:Dispose of according to national and regional provisions. Waste code EWC Nr:
070699 (Group: waste material of MFSU from fats, lubricants, soaps, detergents,
disinfectants and personal protection products). Small amounts of the product (up
to about 500 ml per day) can be disposed of via the sewage system after dilution
1:5 with tap water.Contaminated packaging:Empty packaging can be treated like household waste or recycled after cleaning
with water. Handle the packaging containing the product in the same way as the
product itself. Where available, references to local regulations regarding disposal
are given in section 15 of the SDS. The user has sole responsibility for
acquaintance and compliance with the applicable regulations.

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/ADN/RID)

- **14.1 UN number** UN 1987
- 14.2 UN proper shipping name
 - ALCOHOLS, N.O.S. (Propan-1-ol)
- 14.3 Transport hazard class(es)
- 14.4 Packing group III | Danger label: 3 | LQ: 5 L
- **14.5 Environmental hazards** Environmental hazards: No
- **14.6** Special precautions for user See sections 6 to 8.



Sea transport (IMDG/IMO)

- **14.1 UN number** UN 1987
- 14.2 UN proper shipping name ALCOHOLS, N.O.S. (Propan-1-ol)
- **14.3 Transport hazard class(es)** 3
- 14.4 Packing group III | Danger label: 3 | LQ: 5 L
- 14.5 Environmental hazards Environmental hazards: No Marine pollutant: No
- **14.6** Special precautions for user See sections 6 to 8.
- **14.7** Maritime transport in bulk according to IMO instruments Not applicable for product as supplied.

Air transport (IATA)

- 14.1 UN number UN 1987
- 14.2 UN proper shipping name ALCOHOLS, N.O.S. (Propan-1-ol)
- **14.3 Transport hazard class(es)** 3
- 14.4 Packing group III | Danger label: 3 | LQ: 5 L
- **14.5** Environmental hazards Environmental hazards: No
- **14.6** Special precautions for user See sections 6 to 8.



SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product has been classified and marked in accordance with Regulation (EC) No.1272/2008 (CLP). The product complies with requirements of Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 648/2004 (Detergents Regulation), Regulation (EU) No. 528/2012 (Biocides Regulation), Directive 93/42/EC (Medical Devices Directive), and Regulation (EU) No. 2017/745 on medical devices (MDR), if applicable.

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this product.

SECTION 16: OTHER INFORMATION

Indication of changes

- 1.1 Product identifier Updated.
- 1.2 Relevant identified uses of the substance or mixture and uses advised against Updated.
- 1.3 Details of the supplier of the safety data sheet Updated.
- 1.4 Emergency telephone number Updated.
- 2.3 Other hazards Updated.
- 4.1 Description of first aid measures Updated.
- 5.2 Special hazards arising from the substance or mixture Updated.
- 5.3 Advice for firefighters Updated.
- 6.1 Personal precautions, protective equipment and emergency procedures Updated.
- 6.2 Environmental precautions Updated.
- 7.1 Precautions for safe handling Updated.
- 7.2 Conditions for safe storage, including any incompatibilities Updated.
- 8.1 Control parameters Updated.
- 8.2 Exposure controls Updated.
- 9.1 Information on basic physical and chemical properties Updated.
- 9.2 Other information Updated.

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 / Information on toxicological effects - Updated.

- 11.2 Information on other hazards Updated.
- 12.6 Endocrine disrupting properties Updated.
- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Updated.

Abbreviations and acronyms

- ADN European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR European Agreement concerning the International Carriage of Dangerous Goods by Road

ASTM - American Society for Testing and Materials

AwSV - Ordinance on facilities for handling substances that are hazardous to water

BOD - Biochemical Oxygen Demand

- c.c. Closed cup
- CAS Chemical Abstract Services

CESIO - European Committee of Organic Surfactants and their Intermediates

COD - Chemical Oxygen Demand

DMEL - Derived Minimum Effect Level

DNEL - Derived No Effect Level

EbC50 - Median concentration in terms of reduction of growth

EC - Effective concentration

EINECS - European Inventory of Existing Commercial Chemical Substances

EN - European Norm

ErC50 - Median concentration in terms of reduction of growth rate



GGVSEB - German ordinance for road, rail and inland waterway transportation of dangerous goods GGVSee - German ordinance for sea transportation of dangerous goods GLP - Good Laboratory Practice GMO - Genetic Modified Organism IATA - International Air Transport Association ICAO - International Civil Aviation Organization IMDG - International Maritime Dangerous Goods ISO - International Organization For Standardization LD/LC - Lethal dose/concentration LOAEL - Lowest Observed Adverse Effect Level LOEL - Lowest Observed Effect Level LQ - Limited Quantity M-Factor - Multiplying factor NOAEL - No Observed Adverse Effect Level NOEC - No Observed Effect Concentration NOEL - No Observed Effect Level o.c. - Open cup OECD - Organisation for Economic Cooperation and Development OEL - Occupational Exposure Limit PBT - Persistent, bioaccumulative, toxic PNEC - Predicted No Effect Concentration **REACH - REACH registration** RID - Convention concerning International Carriage by Rail SVHC - Substances of Very High Concern TA - Technical Instructions TRGS - Technical Rules for Hazardous Substances vPvB - Very persistent, very bioaccumulative WGK - Water Hazard Class

Key literature references and sources for data

No data available.

Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard category	Hazard statement code(s)	Classification procedure
Flam. Liq. 3	H226	On basis of test data.
Eye Dam. 1	H318	Harmonised (legal) classification.
STOT SE 3	H336	Harmonised (legal) classification.

List of relevant phrases

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H318 Causes serious eye damage.

H336 May cause drowsiness or dizziness.

Training information

Comply with national laws regulating employee instruction.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.