

Product: OROMED® Gel

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

Product name: OROMED® Gel
 UFI: KS00-V0W2-M00E-05F6
 Substance type: Mixture
 Use of the substance/mixture: Disinfectant

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

Identified uses: OROMED® Gel is a ready-to-use, hydro-alcoholic gel with a broad antimicrobial activity for the surgical and hygienic hand and forearm disinfection. The clear, non-sticky, and residue-free formulation is pleasant to use, dries quickly, and leaves hands feeling velvety smooth. OROMED® Gel incorporates a unique skin protection system, made up of moisturizers, emollients, vitamins, and soothing compounds, shielding even the most sensitive hands from the effects of frequent disinfection. OROMED® Gel provides relief from dryness and irritation. The high content of antioxidants and anti-aging substances neutralizes harmful free radicals, which cause premature aging. OROMED® Gel is free of fragrances, and dyes. The gel is biodegradable.

Uses advised against: Do not use for purposes other than those prescribed.

Recommended restrictions on use: For professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer	
Address:	United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein
Telephone:	+423 237 15 03
Email:	info@udm.li
Website:	www.udm.li
Downstream user/importer/distributor	
Address:	United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein
Telephone:	+423 237 15 03
Email:	info@udm.li
Website:	www.udm.li

Person responsible for preparing the SDS

Lee Moi Wong | Research & Development | Chief Research Officer (CRO)
 Telephone: +423 237 15 03
 Email: info@udm.li

Product: OROMED® Gel

1.4 Emergency telephone number

Emergency telephone number: 112 / +351 808 250 143

* 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. 2	H225	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:



GHS02



GHS05



GHS07

Signal word: Danger

Hazard statements:	H225	Highly 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 + P338	IF IN EYES: Rinse cautiously with water for several minutes. 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.

2.3 Other hazards

PBT or vPvB properties: 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.

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.

Product: OROMED® Gel

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

Classification according to Regulation (EC) No 1272/2008

Substance name	Identification	Classification	SCL, M-factor, ATE	Concentration
Ethanol	CAS no.: 64-17-5 EC no.: 200-578-6 Index no.: 603-002-00-5 REACH no.: 01-2119457610-43-0350	Flam. Liq. 2, H225	No data available.	50% - 100%
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.	15% - < 30%
Propan-2-ol	CAS no.: 67-63-0 EC no.: 200-661-7 Index no.: 603-117-00-0 REACH no.: 01-2119457558-25-0000	Eye Irrit. 2, H319 Flam. Liq. 2, H225 STOT SE 3, H336	No data available.	2.5% - < 5%

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:

No special action required.

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.

After ingestion:

Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything 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.

Product: OROMED® Gel

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: 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).
Additional information: 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.

Product: OROMED® Gel

Consumer (long term, systemic effects)	Inhalation	89 mg/m ³
Worker (long term, systemic effects)	Dermal	888 mg/kg bw/day
Consumer (long term, systemic effects)	Dermal	319 mg/kg bw/day
Consumer (short term, systemic effects)	Oral	51 mg/kg bw/day
Consumer (long term, systemic effects)	Oral	26 mg/kg bw/day

PNEC values

Substance name	Route of exposure	Limit value
Ethanol CAS no.:64-17-5	Fresh water	960 µg/L
	Intermittent release (fresh water)	2.75 mg/L
	Marine water	790 µg/L
	Sewage treatment plant	580 mg/L
	Sediment (fresh water)	3.6 mg/kg dw
	Sediment (marine water)	2.9 mg/kg dw
	Soil	630 µg/kg dw
	Secondary poisoning	380 - 720 mg/kg food
Propan-1-ol CAS no.:71-23-8	Fresh water	6.83 mg/L
	Intermittent release (fresh water)	10 mg/L
	Marine water	683 µg/L
	Sewage treatment plant	96 mg/L
	Sediment (fresh water)	27.5 mg/kg dw
	Sediment (marine water)	2.75 mg/kg dw
	Soil	1.49 mg/kg dw
Propan-2-ol CAS no.:67-63-0	No data available.	No data available.

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures

Eye/face protection:	Not required during normal use.
Hand protection:	Not required during normal use.
Body protection:	Not required during normal use.
Respiratory protection:	Do not inhale gas/vapours/aerosol.
Thermal hazards:	No data available.
Hygiene measures:	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 eyes. 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, slightly viscous gel
Colour:	Colourless
Odour:	Of alcohol
Melting point:	No data available.
Freezing point:	No data available.
Boiling point or initial boiling point	No data available.

Product: OROMED® Gel

and boiling range:	
Flammability:	The product is flammable.
Lower explosion limit:	Not applicable.
Upper explosion limit:	Not applicable.
Flash point:	55 °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:	Completely miscible with water.
Partition coefficient n-octanol/water:	Not applicable.
Vapour pressure at 50 °C:	No data available.
Density:	0.85 g/cm ³
Relative density:	0.85
Relative vapour density at 20 °C:	No data available.

9.2 Other information

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.

Product: OROMED® Gel

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.

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 exposure

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.

11.2 Information on other 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.

Component: No data available.

Product: OROMED® Gel

Other hazards

Mixture: No data available.

Component: No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

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. Based on available data, the biodegradability in sewage treatment plants can be categorized as high. High product concentrations can affect the biodegradability potential of the activated sludge. Obtain the consent of the local authorities before discharging the concentrated solution to wastewater treatment plants.

Substance name	Biodegradation	Basis	Remark
Ethanol	94%	OECD 301 E	No data available.
Propan-1-ol	75%	20 D	Readily biodegradable.
Propan-2-ol	95%	21 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

Product: OROMED® Gel

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. (Ethanol, 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.

Sea transport (IMDG/IMO)

14.1 UN number

UN 1987

14.2 UN proper shipping name

ALCOHOLS, N.O.S. (Ethanol, Propan-1-ol)

14.3 Transport hazard class(es)

3

14.4 Packing group

III | Danger label: 3 | LQ: 5 L

Product: OROMED® Gel

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. (Ethanol, 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

1.3 Details of the supplier of the safety data sheet - Updated.

Abbreviations and acronyms

Product: OROMED® Gel

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. 2	H225	On basis of test data.
Eye Dam. 1	H318	Harmonised (legal) classification.
STOT SE 3	H336	Harmonised (legal) classification.

Product: OROMED[®] Gel

List of relevant phrases

- H225 Highly flammable liquid and vapour.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- 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.