



Safety Data Sheet

according to Regulation (EC) No 1907/2006



Revision date: 01.01.2021
Date of entry into force: 01.01.2021

Version: 9
Replaces version: 1.0

Amosept

This is the English translation of the German SDS (for Germany).
The product is a medicinal product in Germany, there is no obligation to provide a safety data sheet. It was created voluntarily for information for our customers.

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

1.1 Product identifier

Trade name: Amosept

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

Use of the mixture:
Hygienic handwash

1.3 Details of the supplier of the safety data sheet

Department providing information: Department of Science and Technology Berlin

E-mail: kontakt@lysoform.de
Telephone: 030 / 77992-226

Supplier (distributor):

Deutschland

Lysoform Dr. Hans Rosemann GmbH
Kaiser-Wilhelm-Straße 133
D-12247 Berlin
Telefon: 030 / 77992-0
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Schweiz

Lysoform Schweizerische Gesellschaft für Antiseptie AG
Postfach 444
5201 Brugg / Windisch
Telefon: 056 / 4416981
Telefax: 056 / 4424114
info@lysoform.ch

BAG-Zul.Nr.: CHZN1253

1.4 Notfallauskunft

Deutschland

Giftnotruf München Toxikol. Abteilung,
Klinikum rechts der Isar
Ismaninger Str. 22, 81675 München
Telefon: 0049 89 19240
Telefax: 0049 89 4140-2467

Schweiz

Schweizer Toxikologisches Informationszentrum
Freiestrasse 16
8032 Zürich
Telefon: 145 / nur aus der Schweiz
Telefax: 0041 44 2528833

Section 2: Hazards identification

2.1 Classification of the substance or mixture

CLP classification (EG) Nr. 1272/2008:

Flam. Liq.: Kat.3 H226
Eye Irrit.: Kat.2 H319
STOT SE: Kat. 3 H336



Amosept

2.2 Label elements

In the countries of the EU in which the preparation is registered as a medicinal product, there is no labelling according to the CLP regulation (as stated here).

Symbols und signal word:



Warning

Hazard statements:

- H226 Flammable liquid and vapour.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- May cause contact irritative or allergic skin reactions. (No H-statement)

Precautionary statements:

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P305 + IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if easy
- P351 + to do. Continue rinsing.
- P338
- P337 + If eye irritation persists: Get medical advice.
- P313

Hazardous ingredient for labelling:

Propan-1-ol, didecyldimethylammonium chloride und sodium cocoamphoacetate

2.3 Other hazards

The mixture does not meet the criteria for classification as PBT or vPvB.

Section 3: Composition/information on ingredients

3.1 Substances

This product is a mixture.

3.2 Mixtures

Chemical characterization:

Propan-1-ol

EG-No: 200-746-9 CAS-No: 71-23-8 REACh-Reg.no: 01-2119486761-29

Quantity : 18 - 22 %

Flam. Liq.: 2 H225 Highly flammable liquid and vapour.

Eye Dam.: 1 H318 Causes serious eye damage.

STOT SE: 3 H336 May cause drowsiness or dizziness.



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Sodium Cocoamphoacetate

(Reaction products of 1H-Imidazole-1-ethanol, 4,5-dihydro-, 2-(C7-C17 odd-numbered, C17-unsatd. alkyl) derivs. and sodium hydroxide and chloroacetic acid)

EG-No: 931-291-0 REACh-Reg.no: 01-2119487973-19

Quantity : 10 - 13 %

Eye Dam.: 1 H318 Causes serious eye damage.

Didecyldimethylammonium chloride

EG-No: 230-525-2 CAS-No: 7173-51-5

Quantity : 1 %

Acute Tox. 3 H301 Toxic if swallowed.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Aquatic Acute 1 H400 (M=10) Very toxic to aquatic life.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

Citric acid

CAS-No: 5949-29-1 REACh-Reg.no: --

Quantity : 1 %

Eye Irrit.: 2 H319 Causes serious eye irritation.

Section 4: First aid measures

4.1 Description of first aid measures

Immediately seek medical advice. Show the Safety Data Sheet, container or label.

Inhalation:

Supply fresh air.

Eye contact:

Rinse opened eye for several minutes with plenty of drinking water. If eye irritation persists seek medical advice.

Ingestion:

Do not induce vomiting. Rinse mouth with drinking water and give plenty of water to drink.

4.2 Most important symptoms and effects, both acute and delayed

Acute: mucous membrane irritation

Delayed: After oral absorption, interference with the central nervous system, e.g. Dizziness and narcotic effects occur. Facial and skin redness by dilation of the blood vessels.

4.3 Indication of any immediate medical attention and special treatment needed

No information

Section 5: Firefighting measures

5.1 Extinguishing media

Water spray, carbon dioxide, dry powder, alcohol-resistant foam

5.2 Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gas may develop:

For example: carbon monoxide, carbon dioxide and explosive vapour / air mixtures

5.3 Advice for firefighters

Wear self-contained breathing apparatus. Cool endangered containers or persons with water spray.



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Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective gloves and protective clothing. Keep ignition sources away - do not smoke. Ensure adequate ventilation.

6.2 Environmental precautions

Do not allow to reach sewage system / surface or ground water.

6.3 Methods and material for containment and cleaning up

Wipe up with absorbent material (cloth, fleece, sand, universal binders).
Larger quantities: Apply suction cleaning.

6.4 Reference to other sections

Safe handling (section 7), personal protective equipment (section 8) and disposal considerations (section 13)

Section 7: Handling and storage

7.1 Precautions for safe handling

Ensure good ventilation / exhaustion at the workplace. Caution near alcohol-sensitive materials (for example: acrylic, paint, pickling, lacquered jewellery or watches of certain plastic).

Notes on general hygiene measures at the workplace:

Keep away from food. Take off all contaminated clothing immediately. Avoid contact with eyes.

7.2 Conditions for safe storage, including any incompatibilities

Keep temperature below 25°C, frost-free, well ventilated and dry. Keep out of the reach of children. Store in the original container. For the transport conditions, see section 14 above.

Further information about storage conditions

Keep away from heat and direct sunlight.
Keep separate from food.

Information about fire and explosion protection

Can form explosive gas-air mixtures. Good ventilation, especially at floor level. Vapours are heavier than air. Keep ignition sources away - do not smoke. Take measures to prevent electrostatic charging.

Storage class: 3 (TRGS 510)

7.3 Specific end use(s)

No specific end use known.

Section 8: Exposure controls/personal protection

8.1 Control parameters

No

8.2 Exposure controls

Keep away from foodstuff, beverages and feed. Avoid contact with eyes.

Respiratory protection

Not necessary

Skin protection

In order to prevent skin irritations in the professional field, the following is - regardless of the actual contact with disinfectants - recommended:

- Fast skin penetrating care cream in between if needed.
- A greasy cream after washing at the end of work or before work breaks.



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Eye / face protection
Not necessary

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

If no information on the mixture is available, relevant information on ingredients may also be provided in the form "ingredient: indication".

Appearance

- Physical state:	Liquid
- Colour:	Yellowish
Odour:	Characteristic
Odour threshold:	Ethanol: 19 – 93 mg/m ³ (0.001 - 0.0048 Vol.%)
pH (50 g/l) at 20 °C:	Ca. 5,6
Melting point:	Not determined
Initial boiling point / boiling range:	Not determined
Flash point:	31 °C (DIN 51755)
Evaporation rate:	Not determined
Flammability:	Not determined
Explosion limits in air:	Propan-1-ol 2.4 – 10.8 % (Vol.%)
Vapour pressure:	Propan-1-ol: 28.2 hPa bei 25 °C
Vapour density, relative (air = 1):	Not determined
Density at 20 °C:	Ca. 1.0 g/cm ³
Solubility in water:	Any
Partition coefficient n-octanol / water:	For a mixture not applicable.
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not applicable, no known decomposition
Viscosity:	Not determined
Oxidising properties:	Not determined

9.2 Other information

Further physical and chemical data have not been determined.

Section 10: Stability and reactivity

10.1 Reactivity

No hazardous reactions if stored and used as described.

10.2 Chemical stability

No decomposition if stored and used as described.

10.3 Possibility of hazardous reactions

No hazardous reactions if stored and used as described.

10.4 Conditions to avoid

See section 7

10.5 Incompatible materials

No incompatible materials known.

10.6 Hazardous decomposition products

No decomposition if stored and used as described.



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Section 11: Toxicological information

11.1 Information on toxicological effects

The active compounds have been extensively studied with regard to the toxic profile. The exposure is safe if handled as prescribed. In consideration of the mixture no deviant results are expected. The mixture was therefore not examined in all categories. For toxicological effects use the information on hazardous substances.

11.1.1 For the mixture:

Acute toxicity

LD₅₀: Oral rat 4.6 ml/kg/BW

Skin corrosion/irritation

OECD No 404 (Draize): non irritant

Serious eye damage/irritation

OECD 405 rabbit: „irritant“

Other categories

No data available

11.1.2 For the substances:

Propan-1-ol

Acute toxicity:

LD₅₀ rat (oral): ~8000 mg/kg

LC₅₀ rat (inhalativ): > 34 mg/l; 4h; vapor (OECD-guideline 403)

LD₅₀ rabbit (dermal): 4032 mg/kg (literature)

Primary irritant effect:

Skin: No effects

Sensitization:

No sensitization (OECD- guideline 406)

Didecyldimethylammonium chloride

Sensitization: non-sensitizing in guinea pig - Buehler Test Method: US EPA

In rare cases contact-irritative or allergic skin reactions may occur.

Genotoxicity in vitro:

Negative - Ames test on Salmonella typhimurium method: OECD 471

Negative - Chromosome aberration test, CHO cells / negative gene mutation, CHO cells

Genotoxicity in vivo:

Negative chromosome aberration test oral in rats Method: OECD 475

Sodium Cocoamphoacetate

Sensitization:

Guinea pig, OECD 406: non-sensitizing

The substance has no mutagenic activity (Ames test)

Citric acid

Not relevant

Section 12: Ecological information

The mixture was not tested for certain effects. Information on the hazardous substance should be used. Citric acid is not relevant.



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12.1 Toxicity

Propan-1-ol

EC₅₀ / 48 h: 3644 mg/l (Daphnie) (DIN 38412 part 11, static)

LC₅₀ / 96 h: 4555 mg/l (Pimephales promelas)

EC₅₀ / 3h: >1000 mg/l (bacteria) (OECD-Richtlinie 209, aquatic)

NOEC / 21 d: > 100 mg/l, Daphnia magna (OECD Richtlinie 211, semistatic)

Didecyldimethylammonium chloride

LC50: 0.19 mg / l with pimephales promelas, exposure time: 96 h, method: US EPA

NOEC: 0.032 mg / l in Danio rerio, chronic toxicity, exposure time: 34 d with OECD 210

EC50: 0.062 mg / l, Daphnia magna, immobilization, exposure time: 48 h, method: EPA-FIFRA

NOEC: 0.016 mg / l, Daphnia magna, reproduction test, 21 d, method: OECD 211

ErC50: 0.026 mg / l, pseudokirchneriella subcapitata (green alga), growth inhibition, exposure time: 96 h, method: OECD 201

EC50: 11 mg / l, activated sludge, respiratory inhibition, exposure time: 3 h, method: OECD 209

Toxicity to soil organisms:

NOEC: ≥ 1000 mg / kg, Eisenia fetida (earthworms), acute toxicity, Exposure time: 14 d, Method: OECD 207

Toxicity to terrestrial organisms:

EC50: 283 - 1670 mg / kg, Exposure time: 14 d, Method: OECD 208

Sodium Cocoamphoacetate

OECD 203, species Goldorfe: LC0 = 20 mg / l; LC50 = 28 mg / l; LC100 = 40 mg / l

OECD 202, species Daphnia magna, 24h: EC50 18 mg / l

OECD 202, species Daphnia magna, 48h: EC50 6.4 mg / l

OECD 201, species Scenedesmus subspicatus, 72h: EbC50 = 22 mg / l; EbC10 = 6.75 mg / l

12.2 Persistence and degradability

Propan-1-ol

Easily biodegradable (OECD)

Didecyldimethylammonium chloride

Stability in water: Abiotic degradation, hydrolytically stable, Method: EPA-FIFRA

Modified Storm Test: 72%, Readily biodegradable, Test Duration: 28 days, Method: OECD 301 B

The-away test: 93.3%, trial period: 28 d

OECD confirmatory test: 91%, test duration 24-70 d, method: OECD 303 A

The surfactant complies with the biodegradability criteria as laid down in Regulation (EC) 648/2004 on detergents.

Sodium cocoamphoacetate

Biodegradability: DIN 38412 T.25, 28d: 77% / OECD 301 A, 28d: readily degradable, 73%

Chemical Oxygen Demand (COD), DIN 38409 T.41: 992.000mg / l

12.3 Bioaccumulative potential

Propan-1-ol

No bioaccumulation is to be expected.

Didecyldimethylammonium chloride and Sodium cocoamphoacetate

No data

12.4 Mobility in soil

Propan-1-ol

The product is mobile in an aqueous environment.

Didecyldimethylammonium chloride and Sodium cocoamphoacetate

No data

12.5 Results of PBT and vPvB assessment

The mixture does not contain any substances that are assessed as PBT or vPvB.



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12.6 Other adverse effects

The mixture is classified as water hazard class 2 (by German AwSV).

Section 13: Disposal considerations

13.1 Waste treatment methods

Treatment of the mixture

Disposal in compliance with local regulations. Waste should not be disposed of via wastewater.

Treatment of contaminated packaging

Completely emptied containers can be recycled.

Waste code according to AVV

07 06 04 for the product
15 01 02 for the primary packaging

Relevant EU or other regulations

German law: KrW-/AbfG (Kreislaufwirtschafts- und Abfallgesetz)

Section 14: Transport information

Assessments of the transport stability tests of our medicinal products showed that no specific transport conditions (e.g. temperature) have to be observed and recorded in the temperate climates according to the "Good Distribution Practice".

14.1 UN-number: 1993

14.2 Proper shipping name

All modes of transport:
FLAMMABLE LIQUID, N.O.S. (n-propanol, quaternary ammonium compound)

14.3 Transport hazard class(es)

Land: ADR/RID and GGVS/GGVE class: 3
Tunnel restriction code: D/E
Sea: IMDG/GGV Sea-class: 3
EMS-number: F-E, S-E
Air: ICAO-TI / IATA-DGR-class: 3

14.4 Packing group

III

14.5 Environmental hazards

Labelling environmentally hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: No
IMDG-Code: Marine Pollutant: No

14.6 Special precautions for user (transport company)

No

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No transport in bulk



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Section 15: Regulatory information

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

EU-regulations:

1907/2006 REACH / 1272/2008 CLP GHS / 528/2012 Biocidal products / 98/24/EG Risks related to chemical substances / 648/2004 Detergents

German regulations:

Arzneimittelgesetz mit entsprechenden Verordnungen / Chemikaliengesetz ChemG / Gefahrstoffverordnung GefStoffV / TRGS und Bekanntmachungen / Betriebssicherheitsverordnung BetrSichV / Jugendarbeitsschutzgesetz / Mutterschutzgesetz / Guidelines Berufsgenossenschaften

Other information:

The product is approved differently in the countries.
Germany: Medicinal products in accordance with AMG § 2 (1).

15.2 Chemical safety assessment

For this mixture no chemical safety assessment has been carried out.

Section 16: Other information

Changes since the publication of the previous version

Version 9: completely revised / Version number of the SDS is now similar to the German SDS

Literature and data sources

TRGS / Gestis / professional associations / MSDS of ingredients

Methods in accordance with Article 9 of Regulation (EC) no. 1272/2008 used to evaluate the information for the purpose of classification.

Classification was based on tests, the components and the physical and chemical properties.

The data contained in this Safety Data Sheet are based on our current knowledge and experience and describe the product with regard to the safety requirements. The information should not be regarded in any way as a description of the nature of the goods (product specification). Any agreed property or the suitability of the product for a specific purpose can not be derived from our information in the Safety Data Sheet. We will advise you whether, the preparation is suitable for a defined purpose. Any proprietary rights and existing laws and regulations must be observed by the recipient of our product (responsibility of the recipient).