



Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 19.11.2018
Date of entry into force: 19.11.2018

Version: 9
Replaces version: -

Hospisept und Hospisept gefärbt

This is the English translation of the German SDS (for Germany).

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

1.1 Product identifier

Trade name: Hospisept und Hospisept gefärbt

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

Use of the mixture:

Disinfection

For professional use

1.3 Details of the supplier of the safety data sheet

Department providing information: Department of Science and Technology Berlin

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Telephone: +49 30 77992-226

Supplier (distributor):

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1.4 Emergency telephone number

Germany

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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



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2.2 Label elements

In EU countries where the product is registered as a medicinal product, no labelling is made according to the CLP Regulation (as indicated here).

Symbols and signal word:



Warning

Hazard statements:

H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves and eye protection.
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 and Ethanol

2.3 Other hazards

The mixture does not meet the criteria for classification as PBT or vPvB.
In exceptional situations (for example: fumigation, effect of heat or leakage of large amounts in unventilated spaces) it may form explosive air mixtures.

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 : 50 - 60 %

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

Eye Dam.: Kat.1 H318 Causes serious eye damage.

STOT SE: Kat.3 H336 May cause drowsiness or dizziness.



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Ethanol

EG-No: 200-578-6 CAS-No: 64-17-5 REACh-Reg.no: 01-2119457610-43

Quantity : 10 - 20 %

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

Eye Irrit.: Kat.2 H319 Causes serious eye irritation.

Section 4: First aid measures

4.1 Description of first aid measures

General information:

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

Inhalation:

Supply fresh air.

Skin contact:

n.a.

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

Alcoholic vapours are heavier than air and may spread along floors.

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

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

Notes for safe handling:

Ensure good ventilation / exhaust 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

Requirements for storage rooms and containers

Keep cool, but frost-free and not over 25 °C, well ventilated and dry. Keep out of the reach of children. Store in the original container.

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.



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Section 8: Exposure controls/personal protection

8.1 Control parameters

| Ingredient | CAS-No | Value | Base |
|-------------------|---------------|---|-------------|
| Ethanol | 64-17-5 | Occupational Exposure Limits: 380 mg/m ³ , 200 ml/m ³ 4(II) DFG, Y | TRGS 900 |

8.2 Exposure controls

Individual protection measures - Personal protective equipment:

General health and safety measures

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

Respiratory protection

With good room ventilation, respiratory protection is not necessary.

In exceptional circumstances a respirator with filter A (EN 14387) may be used.

Hand protection

In order to avoid skin discoloration the medical staff should wear gloves when working with the coloured preparation. Otherwise not required.

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.

Eye / face protection

Normally not required

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

Odour: Characteristic

Odour threshold: Ethanol: 19 – 93 mg/m³ (0.001 - 0.0048 Vol.%)

pH at 20 °C: Ca. 8

Melting point: Ethanol: -114.5 °C (OECD 102)

Propan-1-ol: -127.05 °C

Initial boiling point / boiling range: Ethanol: 78 °C

Propan-1-ol: 97 °C

Flash point: 26 °C (DIN 51755)

Evaporation rate: Not determined

Flammability: Not determined

Explosion limits in air: Ethanol: 2.5 – 15 % (Vol.%)

Propan-1-ol 2.4 – 10.8 % (Vol.%)

Vapour pressure: Ethanol: 59 hPa / 20 °C

Propan-1-ol: 28 hPa / 25 °C



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Vapour density, relative (air = 1): Ethanol: 1.59
Density at 20 °C: Ca. 0.9 g/cm³
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

Acute toxicity dermal (rat): LD₅₀ = 15.4 ml/kg BW

Subacute toxicity oral (rat): NOEL = 1.0 % (4 weeks)

Acute toxicity dermal (rabbit) LD₅₀ = >9.4 ml/kg BW

Acute toxicity inhalation (rat): not toxic

Subacute toxicity inhalation (rat): acceptable limit concentration 160 mg/m³ (safety factor 10)

Skin corrosion/irritation

Clinical study (BioSkin Report No: 20917BS): no corrosive or irritating effects on intact skin

primary skin irritation (rabbit): non-toxic

Serious eye damage/irritation

Eye irritation to rabbits: slightly irritating

Respiratory or skin sensitisation

Studies of Hospisept on guinea pigs: No sensitization

Germ cell mutagenicity

Ames test: no gene mutations

Carcinogenicity

Micronucleus test on Hospisept: No chromosome mutations

Reproductive toxicity

No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration hazard

No data available

Symptoms and effects (delayed and chronic) with details of the routes of exposure

Also: information on toxicokinetics, metabolism and distribution

No data available

11.1.2 For the substance:

Ethanol

Germ cell mutagenicity : It is not considered to be mutagenic.
OECD 471 / 475 / 476 / 473 / 471

Teratogenicity : No effects on or through the lactation



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Symptoms:

Shortness of breath, drowsiness, unconsciousness, drop in blood pressure, vomiting, coughing, headache, intoxication, drowsiness, mucosal irritation, dizziness, nausea

Experiences with humans:

Excessive use of alcohol during pregnancy induces Foetal Alcohol Syndrome (reduced birth weight, physical and mental disorders).

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)

Section 12: Ecological information

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

12.1 Toxicity

Ethanol

Toxicity:

LC₅₀ in 96 h: 13000 mg/l (Oncorhynchus mykiss) OECD 203 (Fish, Acute Toxicity Test)

LC₅₀ in 48 h: 12340 mg/l (Daphnia magna)

Propan-1-ol

Toxicity:

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)

12.2 Persistence and degradability

Ethanol

97% OECD 301 B (Ready Biodegradability - CO₂ Evolution Test)

Propan-1-ol

Easily biodegradable (OECD)

12.3 Bioaccumulative potential

Ethanol

BCF: 3.2 mg/l Log Pow: -0.32

Propan-1-ol

No bioaccumulation is to be expected.



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12.4 Mobility in soil

Ethanol

No data available

Propan-1-ol

The product is mobile in an aqueous environment.

12.5 Results of PBT and vPvB assessment

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

12.6 Other adverse effects

The mixture is classified as water hazard class 1 (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 05 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

Evaluations of transport stability testing of our drugs have shown that in temperate climates, no specific transport conditions (e.g. temperature) must be adhered to and recorded according to the Good Distribution Practice.

14.1 UN-number: 1987

14.2 Proper shipping name

All modes of transport: ALCOHOLS, N.O.S. (1-propanol, ethanol)

14.3 Transport hazard class(es)

Land: ADR/RID and GGVS/GGVE class: 3
Tunnel restriction code: D/E LQ 7

Sea: IMDG/GGV Sea-class: 3
EMS-number: F-E, S-D

Air: ICAO-TI / IATA-DGR-class: 3

14.4 Packing group

III



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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

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 / 98/24/EG Risks related to chemical substances / 648/2004 Detergents

German regulations:

Chemikaliengesetz ChemG / Gefahrstoffverordnung GefStoffV / TRGS und Bekanntmachungen / Betriebssicherheitsverordnung BetrSichV / Jugendarbeitsschutzgesetz / Mutterschutzgesetz / Guidelines Berufsgenossenschaften

Other information:

Authorization Germany: Medicinal product 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: First English version / Version number of the SDS is 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).