according to Regulation (EC) No 1907/2006

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Blanisol-Pur

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: Blanisol-Pur

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

Use of the mixture:

Cleanser for instruments and medical devices For professional use

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: +49 30 77992-216

Supplier (distributor):

Lysoform Dr. Hans Rosemann GmbH

Kaiser-Wilhelm-Str. 133

D-12247 Berlin

Tel.: +49 30 / 77992-0 Fax: +49 30 / 77992-219

www.lysoform.de

1.4 Emergency telephone number Germany

Munich toxicological department Klinikum rechts der Isar Ismaninger Str. 22, 81675 Muenchen

Tel.: +49 89 19240 Fax: +49 89 4140-2467

Section 2: Hazards identification

2.1 Classification of the substance or mixture

CLP classification (EG) Nr. 1272/2008:

Eye Dam. 1 H318 Aquatic Chronic 3 H412

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2.2 Label elements

Symbol und signal word:



Hazard statements:

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P280 Wear protective gloves and eye protection.

P305 + IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

P351 + present and easy to do. Continue rinsing.

P338

P310 Call doctor immediately.

Hazardous ingredient for labelling:

Alkyldimethylbenzylammonium chloride and Isotridecanol ethoxylated

2.3 Other hazards

The ingredients (from 0.1%) do not meet the criteria for classification as PBT or vPvB and no endocrine disrupting properties are known.

Section 3: Composition/information on ingredients

3.1 Substances

This product is a mixture.

3.2 Mixtures

Chemical characterization:

Alkyldimethylbenzylammonium chloride

EG-No: 270-325-2 CAS-No: 68424-85-1

Quantity: < 1.5 %

Acute Tox. 4 H302 Harmful if swallowed.

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

Aguatic Acute 1 H400 Very toxic to aguatic life. (M=10)

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

Met. Corr. 1 H290 May be corrosive to metals.

Isotridecanol ethoxylated

EG-Nr.: 931-138-8 CAS-Nr.: 69011-36-5 REACH-Registrierungsnr.: No (Polymer)

Quantity: 15 - 30 %

Acute Tox. 4 H302 Harmful if swallowed. Eye Dam. 1 H318 Causes serious eye damage.

Labelling for contents according to Regulation (EC) Nr. 648/2004

Nonionic surfactants: 15 - 30 %, contains parfume

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Section 4: First aid measures

4.1 Description of first aid measures

Always consult a doctor if symptoms persist. Show the Safety Data Sheet, container or label.

Inhalation:

Supply fresh air.

Skin contact:

Take off all contaminated clothing immediately. Rinse skin with plenty of water.

Eve contact:

Rinse opened eye for several minutes with plenty of drinking water and seek medical advice immediately.

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

Mucosal irritation, malaise

4.3 Indication of any immediate medical attention and special treatment needed

No information

Section 5: Firefighting measures

5.1 Extinguishing media

CO₂, powder, water spray or 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 and carbon dioxide

5.3 Advice for firefighters

Wear self-contained breathing apparatus. Wear fully protective suit.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

To make a dilution add water first then add the product. Ensure good ventilation / exhaustion at the workplace.

Notes on general hygiene measures at the workplace:

Wash hands before break and after work. Keep away from food. Take off all contaminated clothing immediately. Avoid contact with eyes.

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7.2 Conditions for safe storage, including any incompatibilities

Store cool but frost-free, well ventilated, dry and out of reach of children.

Store in the original container.

Further information about storage conditions

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

Storage class: 12 (TRGS 510) for Germany

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

General health and safety measures

Keep away from foodstuff, beverages and feed. Take off all contaminated clothing immediately. Wash hands before breaks and at end of work. Avoid contact with skin and eyes.

Respiratory protection

Not required

Hand protection

Impermeable gloves. The wearing of liquid-tight gloves, without changing over four hours daily, is to be regarded as stressful and may not be a permanent measure.

Penetration time of glove material

The resistance of gloves is dependent on many features (material, layer thickness, manufacturer, temperature, stress and duration of contact) and not predictable in advance. Each user has to test the resistance of the gloves for his personal use. Penetration times according to EN 374 are specified by manufacturers and provide guidance for the comparison of gloves.

Material recommendations

Nitrile rubber Butyle rubber

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

When handling the concentrated product (decanting), use tight-fitting eye protection.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state: Liquid
- colour: Yellowish
Odour: Not determined
Odor threshold: Not determined

pH (50 g/l H₂O) at 20 ° C: ca. 8

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Melting point: Not determined Initial boiling point / boiling range: Not determined

Flash point: > 70 °C

Evaporation rate:

Flammability:

Explosion limits in air:

Vapour pressure:

Vapour density, relative (air = 1):

Density at 20 ° C:

Not determined

Not determined

Not determined

ca. 1.0 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

Explosive properties: The product is not explosive.

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 when stored and handled as described.

10.2 Chemical stability

No decomposition if stored and used as described.

10.3 Possibility of hazardous reactions

No hazardous reactions if 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 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 relevant hazardous substances.

11.1.1 For the mixture: No data available

11.1.2 For the relevant substance:

Alkyldimethylbenzylammonium chloride (50% aqueous solution)

Acute toxicity:

LD₅₀ oral: 795 mg/kg (rat)

ATE mix dermal: >5000 mg/kg (calculated)

Primary irritant effect:

Substance 100% dermal rabbit "corrosive" OECD 404

Based on the skin test data: eye damage

Sensitization:

Substance 100% OECD 406 (MKA) guinea pigs: no sensitization

CMR-effects:

Not regarded as CMR.

Isotridecanol ethoxylated

 LD_{50} rat oral: > 300 - 2.000 mg/kg

Section 12: Ecological information

The mixture was not tested for certain effects. For information use the information on the relevant hazardous substance listed below.

12.1 Toxicity

Alkyldimethylbenzylammonium chloride

Aquatic toxicity:

EC₅₀ / 48 h 0,016 mg/l (daphnie)

EC₅₀ / 72 h 0,025 mg/l (selenastrum capricornutum) (OECD 201)

LC₅₀ / 96 h (static) 0,085 mg/l (Rainbow trout) (OECD 203)

NOEC / 21 d 0,025 mg/l (daphnie) OECD 211 S575

EC₁₀ / 72 h 0,0025 mg/l (selenastrum capricornutum) (OECD 201) S 470

Ecotoxical effects:

- \bullet Behaviour in sewage plants: EC $_{20}$ / 0.5 h 5 mg / I (activated sludge organisms) OECD 209
- Depending on the concentration of a toxic effect on activated sludge organisms is possible.

12.2 Persistence and degradability

Alkyldimethylbenzylammonium chloride and surfactants

The surfactant complies with the biodegradability criteria as laid down in Regulation (EC) No 648/2004 on detergents.

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12.3 Bioaccumulative potential

Alkyldimethylbenzylammoniumchlorid

No accumulative potential: Log Kow 2.88; OECD 107 (shake flask method)

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

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

12.6 Endocrine disrupting properties

Endocrine disrupting properties for the environment are not known.

12.7 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 01 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

No dangerous good in terms of transport regulations

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 / (EU) 649/2012

Other information:

Medical device class I CE 0482 according to German Medical Devices Act

15.2 Chemical safety assessment

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

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Section 16: Other information

Changes since the last version

Version 6: First English version / Version number of the SDS is similar to the German SDS

Version 7: New company logo

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 the components

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 and under what circumstances, 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).

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