



Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 12.01.2022
Date of entry into force: 12.01.2022

Version: 11
Replaces version: 10

Lysoformin 3000

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: Lysoformin 3000

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

Use of the mixture:

Disinfection of medical devices or others objects and surfaces.
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 77992-226

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:

Acute Tox. 4 H302 Harmful if swallowed.

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

Flam. Liq. 3 H226 Flammable liquid and vapour.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Muta. Kat. 2 H341 Suspected of causing genetic defects.

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.



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2.2 Label elements

Symbols und signal word:



Danger

Hazard statements:

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

EUH071 Corrosive to the respiratory tract.

H226 Flammable liquid and vapour.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H317 May cause an allergic skin reaction.

H341 Suspected of causing genetic defects.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves, protective clothing and eye protection.

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

P351 + present and easy to do. Continue rinsing.

P338

P303 + IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/

P361 + shower.

P353

P304 + IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P340

P310 In case of accident: Call doctor immediately.

Hazardous ingredients for labelling:

Glutaral, Glyoxal, Didecyldimethylammonium 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:

Glutaral EC-No: 203-856-5 CAS-No: 111-30-8 REACh-Reg. No: 01-2119455549-26

Quantity : 9 - 10 %

Acute Tox. 3 H301 Toxic if swallowed. Acute Tox. 2 H330 Fatal if inhaled.

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

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin Sens. 1A H317 May cause an allergic skin reaction.

Aquatic Acute 1 H400 Very toxic to aquatic life.

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

EUH071 Corrosive to the respiratory tract.



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Glyoxal

EG-No: 203-474-9 CAS-No: 107-22-2 REACH-Reg. No: 01-2119461733-37

Quantity : 7 - 8 %

Acute Tox. 4 H332 Harmful if inhaled. (Aerosol)

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Eye Irrit. 2 H319 Causes serious eye irritation.

Muta. Kat. 2 H341 Suspected of causing genetic defects.

STOT SE: Kat. 3 H335 May cause respiratory irritation.

Didecyldimethylammonium chloride

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

Quantity : 8 – 11 %

Acute Tox. 3 H301 Toxic if swallowed.

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

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

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

Isotridecanol (ethoxylated)

EC-No: 931-138-8 CAS-No: 69011-36-5 REACH-Reg. No: no (Polymer)

Quantity : 5 - 9 %

Acute Tox. 4 H302 Harmful if swallowed.

Eye Dam. 1 H318 Causes serious eye damage.

Propan-2-ol

EG-No: 200-661-7 CAS-No: 67-63-0 REACH-reg.no: 01-2119457558-25

Quantity : < 3 %

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

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

Eye Irrit. 2 H319 Causes serious eye irritation.

Labelling for contents according to Regulation (EC) No 648/2004

Non-ionic surfactants: 5 - 15 %, Perfume, AMYL CINNAMAL, BENZYL SALICYLATE, CITRONELLOL and HEXYL CINNAMAL

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:

Remove person to fresh air and keep comfortable for breathing.

Skin contact:

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

Eye contact:

Rinse opened eye for 10 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 or etching, headache, feeling unwell

Skin contact causes the skin to turn yellow, which usually disappears within a week.

4.3 Indication of any immediate medical attention and special treatment needed

Therapy as with chemical burns.



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Section 5: Firefighting measures

5.1 Extinguishing media

CO₂, powder or water spray, 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. Cool endangered containers with water spray.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment and respiratory protection. 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 at the workplace. When disinfecting surfaces, no puddles must remain. Close the container tightly after use. To make a dilution always add water first, then add the product.

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.

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: 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

Substance	CAS-No	Value	Basis
Glutaral	111-30-8	AGW: 0,2 mg/m ³ , 0,05 ml/m ³ 2(l); Sonstige Angaben: AGS, Sah, Y	TRGS 900

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

In well ventilated areas the short-term handling of the concentrate (preparation of a dilution) can be done without respiratory protection. Use dilutions only in well-ventilated areas. If there is insufficient ventilation, use a respirator with a multi-range filter ABEK.

Hand protection

Impermeable gloves

Wearing liquid-tight gloves (without changing them) for four hours a day is stressful and should not be a constant 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
Butyl rubber

Skin protection

Protective suit

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 product (e.g. decanting) use tight-closing eye protection.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state: Liquid
- Colour: Blue

Odour: Characteristic

Odor threshold: Not determined

pH (50 g/l H₂O) at 20 °C: ca. 7

Melting point: Not determined

Initial boiling point / boiling range: Not determined

Flash point: > 53 °C (DIN 51755)



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Evaporation rate:	Not determined
Flammability:	The product is not self-igniting.
Explosion limits in air:	Not determined
Vapour pressure:	Not determined
Vapour density, relative (air = 1):	Not determined
Density at 20 ° C:	ca. 1,05 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
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

Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as described.

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:

Acute toxicity

Oral with SPF-Wistar rats LD₅₀ (24h) = 1.69 ml / kg body weight; LD₅₀ (14d) = 1.16 ml / kg body weight

Dermal in rats LD₅₀ (24h) = > 8.0 ml / kg BW; LD₅₀ (14d) = > 8.0 ml / kg BW non-toxic

Inhalation based on OECD 403:

Nebulization rats; 4h exposure: LC₅₀ (14d) 6.0 µl / l - practically non-toxic



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Skin corrosion/irritation

OECD 405 on rabbits: dilution 1%: not irritant (non irritant)

Serious eye damage/irritation

No data available

Respiratory or skin sensitisation

sensitizing

Other categories:

No data available

11.1.2 For the relevant substances:

Glutaral

Acute toxicity:

LD₅₀ rat (oral): ca. 77 mg/kg (OECD-guideline 401)

LC₅₀ rat (inhalativ): 0.28 - 0.39 mg/l 4 h (OECD-guideline 403)

An aerosol was tested.

Primary irritant effect:

Skin rabbit: corrosive. (OECD-guideline 404)

Eyes rabbit: irreversible effects (Draize-test)

Sensitization:

Open epicutaneous test (OET) guinea pig: skin sensitizing

Other relevant toxicity

Toxicological data refer to the anhydrous substance.

Glyoxal (40% solution in water)

Acute toxicity:

LD₅₀ rat (oral): ca. 3300 mg/kg (OECD-guideline 401)

LC₅₀ rat (inhalativ): 2.44 mg/l 4 h (OECD-guideline 403)

An aerosol was tested.

Mutagenicity:

Although the substance showed a different test systems in microorganisms and cell cultures

Mutagenic effect, but this could not be confirmed in tests on mammals.

Mutagenic effects can not be ruled out on the basis of experimental data.

Didcyldimethylammonium chloride

Acute toxicity:

LD₅₀ oral: 238 mg/kg (rat) method: OECD 401

LD₅₀ dermal 3342 mg/kg rabbit

Isotridecanol, ethoxylated

Eye damage: Rabbit: May cause irreversible eye damage.

Section 12: Ecological information

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

12.1 Toxicity

Glutaral

Acute very toxic to aquatic organisms. In biological treatment plants interferences of degradation activity of activated sludge are possible depending on local conditions and existing concentrations.

The raw material has not been tested. The data were derived from data for a preparation or mixture with a lower substance concentration.



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Fish toxicity:

LC₅₀ (96 h) 6,2 mg/l, *Cyprinodon variegatus* (Fishtest acute, static)

LC₅₀ (96 h) 0,8 mg/l, *Salmo gairdneri*, syn. *O. mykiss*

The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates:

EC₅₀ (48 h) 2,1 mg/l, *Daphnia magna* (test acute, static)

The details of the toxic effect relate to the nominal concentration.

EC₅₀ (96 h) 0,78 mg/l, *Crassostrea virginica* (OPP 72-3 (EPA-guideline), flow)

The details of the toxic effect relates to the analytically determined concentration.

Aquatic plants:

EC₅₀ (72 h) 0,6 mg/l (growth rate), *desmodemus subspicatus* (OECD 201, static)

NOEC (72 h) 0,025mg/l, *desmodemus subspicatus* (OECD 201, static)

The details of the toxic effect relates to the analytically determined concentration.

Glyoxal (40% solution in water)

Fish toxicity:

LC₅₀ (96 h): 460 - 680 mg/l, *Leuciscus idus* (DIN 38412 part 15, static)

Chronic toxicity to aquatic invertebrates:

NOEC (21 d): 3,19 mg/l, *daphnia magna* (OECD-guideline 211, semistatic)

Didecyldimethylammonium chloride

Fish toxicity:

LC₅₀: 0.19 mg/l *pimephales promelas*, 96 h, method: US-EPA

NOEC: 0.032 mg/l *danio rerio*, chronic toxicity / 34 d / OECD 210

Daphnia toxicity:

EC₅₀: 0.062 mg/l, *daphnia magna*, immobilization, 48 h, method: EPA-FIFRA

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

12.2 Persistence and degradability

Mixture:

DIN 38412 part 25: 90% in 17 days; corresponds to easily degradable

12.3 Bioaccumulative potential

Mixture:

An accumulation in organisms is not to be expected.

12.4 Mobility in soil

Glutaral

From the water surface, the substance does not evaporate into the atmosphere.

Binding to the solid soil phase is possible.

Glyoxal

From the water surface, the substance does not evaporate into the atmosphere.

A binding to the solid soil phase is not expected.

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 3 (by German AwSV).



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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

14.1 UN-number

2924

14.2 Proper shipping name

All modes of transport:
FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Glutaral, Didecyldimethylammoniumchloride)

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-C

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

14.4 Packing group

III

14.5 Environmental hazards

Labelling environmentally hazardous substances

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

14.6 Special precautions for user (transport company)

No

14.7 Maritime transport in bulk according to IMO instruments

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 / 98/24/EG Risks related to chemical substances / 648/2004 Detergents / (EU) 649/2012

German regulations:

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

Other information:

Medical device class IIb CE 0482 according to the German Medical Devices Act
Biocide: BAuA reg.-no. N-12657, N-12658, N-12659

15.2 Chemical safety assessment

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

Section 16: Other information

Changes since the last version

Version 9.1: completely revised
Version 10: 14.5
Version 11: 15.1 Medical device class IIb

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 and test results.

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).