

Safety Data Sheet
according to Regulation (EG) no. 1907/2006



Revision date : 01.11.2012
Coming in force: 01.12.2012

Version: 5
replaces version: 4

Lysoformin® 3000

1. Product and Company Identification

1.1 Product information

Trade name: Lysoformin® 3000

1.2 Relevant identified applications of the compound and applications which should be avoided

Applications of the product

Disinfection by wiping and immersion/soaking of medical devices and other objects and surfaces.
For professional use.

1.3 Particulars about the supplier, who provides the Safety Data Sheet

Informing department: Scientific-Technical Department Berlin
E-Mail: kontakt@lysoform.de
Telefon: 030/77992-216

Manufacturer / Supplier:
Germany

Lysoform Dr. Hans Rosemann GmbH
Kaiser-Wilhelm-Straße 133
D-12247 Berlin
Telefon: 030/77992-0
Telefax: 030/77992-219
www.lysoform.de

Switzerland

Schweizerische Gesellschaft für Antiseptie AG
Postfach 444
5201 Brugg / Windisch
Telefon: 056 / 4416981
Telefax: 056 / 4424114

1.4 Emergency Overview:

Germany

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

Switzerland

Schweizer Toxikologisches Informationszentrum
Freiestrasse 16
8032 Zürich
Telefon: 0041 44 2515151
Telefax: 0041 44 2528833

2. Hazard Identification

2.1 Classification of the substance or product

According to Directive 1999/45/EG:
C; R10; R 20/22; R 34; R 42/43; R 68

2.2 Labelling:

According to Directive 1999/45/EG:

Danger symbol:



C

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Hazard warnings:

- R 10 Flammable.
- R 68/20/22 Harmful: possible risk of irreversible effects through inhalation and if swallowed.
- R 34 Causes burns.
- R 42/43 May cause sensitization by inhalation and skin contact.

Safety considerations:

- S 7 Keep container tightly closed.
- S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S 35 This material and its container must be disposed of in a safe way.
- S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
- S 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- S 51 Use only in well-ventilated areas.

Hazard determining components for labelling

Glutaral, Glyoxal and didecyl dimethyl ammonium chloride

2.3 Other hazards

The product does not meet the criteria for the classification as PBT and/or vPvB.

3. Composition / Information on the Ingredients

3.1 Substances

This product is a mixture of substances.

3.2 Product

Active Substances and hazard determining components

Glutaral

EG-No.: 203-856-5 CAS-No.: 111-30-8 REACH-Registration No.: 01-2119455549-26

Proportion: 9 -10 %
Classification according to directive 67/548/EC:

T; C; N; R 23/25-34-42/43-50

Classification according to ordinance (EC) no. 1272/2008:

Substances or product corrosive on metals: Category 1
Acute toxicity: Cat. 3 (oral)
Acute toxicity: Cat. 3 (inhalation – fog)
Burns or irritation on/of the skin: Cat. 1B
Sensitisation of the respiratory tract: Cat. 1
Sensitisation of the skin: Cat. 1
Hazardous to aquatic environment, acute hazard: Cat. 1
H314; H331; H301; H334; H317; H400; H290

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Glyoxal

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

Proportion: 7 - 8 %

Classification according to Directive 67/548/EC:

Xn; R20-36/37/38-43-68

Classification according to Ordinance (EC) No.1272/2008:

Acute toxicity (inhalation - mist): Cat. 4

Corrosive/irritant to skin: Cat. 2

Skin sensitization: Cat. 1

Severe damage or irritation to eyes: Cat. 2

Germ cell mutagenicity: Cat.2

Specific target organ toxicity (after single exposure): Cat. 3 (irritating to respiratory system)

H315; H317; H319; H332; H335; H341

Didecyl dimethyl ammonium chloride

EG no.: 230-525-2 CAS-no.: 7173-51-5

Proportion: 8 - 11 %

Classification according to Directive 67/548/EC:

C; R 22; R 34

Classification according to Ordinance (EC) No. 1272/2008:

Acute toxicity: Cat. 3 ; H301

Burns on skin: Cat. 1B; H314

Isotridecanol, ethoxylated

EG-No.: 931-138-8 CAS-No.: 69011-36-5 REACH-Registration No.: none (Polymer)

Proportion: 5 - 9 %

Classification according to directive 67/548/EC:

Xn; Xi; R 22-41

Classification according to ordinance (EC) no. 1272/2008:

Acute toxicity: Cat. 4 (oral) H302

Severe eye damage: Cat. 1 H318

Ordinance (EU) no 648/2004 on Detergents / Labelling of the components

Non-ionic surfactants 5 - 15 %

Perfumes, AMYL CINNAMAL, BENZYL SALICYLATE, LILIAL, CITRONELLOL

(For the wording of the listed risk phrases refer to section 16)



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4. First Aid Measures

4.1 Description of the First Aid Measures

General information:

Seek medical advice immediately and show Safety data sheet, package or label.

After inhalation:

Plenty of fresh air.

After skin contact:

Remove immediately all clothing which is soiled or wet with the product.

Rinse out with plenty of water.

After eye contact:

Rinse out with plenty of drinking water with the eyelid held wide open during 10 minutes.

Seek medical advice immediately after rinsing.

After swallowing:

Rinse mouth with drinking water, and then drink plenty of water. Call emergency centre.

4.2 Most important symptoms and effects appearing immediately or later

Irritation of the mucous membranes, headache feeling unwell.

4.3 Medical first aid or special treatments

Information for the doctor:

Therapy like for chemical burns. If the patient swallowed the product, give him big amounts of water (eventually with added Polysiloxanes against foam formation) and induce vomiting mechanically immediately. After swallowing quaternary ammonium compounds a systemic effect like the one caused by curare sets in fast.

5. Firefighting Measures

5.1 Extinguishing media

Suitable extinguishing media:

Water jet, carbon dioxide, extinguishing powder, alcohol-resistant foam.

5.2 Specific hazards coming from the components or the product

While burning some dangerous fumes / gases might be released:

Carbon monoxide, carbon dioxide

5.3 Further information for fire fighting

Wear an atmosphere independent breathing apparatus in the danger area. Use water jets for protection of persons and to cool down containers within the danger zone.



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6. Accidental Release Measures

6.1 Personal precautions, protective equipment and procedures to be used in case of emergency situations

Wear adequate protective gloves, clothes and respiratory protection. Provide for enough ventilation.

6.2 Environmental precautions

Do not allow into sewer system or groundwater.

6.3 Methods and materials for retention and cleaning

Soak up with absorbent materials for ex. cloths, fleece and with liquid-binding materials (sand, universal binder, saw dust). Discard big amounts of liquid with a pump.

6.4 Reference to other Data

Safe Handling (Section 7), Personal Protection (Section 8) and Elimination (Section 13).

7. Handling and Storage

7.1 Protection for a safe handling

Safe handling:

Ensure adequate ventilation at workplace. After disinfection of surfaces make sure that no puddles are left on the ground. Tightly close containers after use. To prepare a dilution always pour in water first and add product afterwards.

General hygienic measures at workplace:

Wash hands before breaks and at the end of the working shift. Keep away from foodstuffs. Take off soiled, wet clothing immediately. Avoid contact with the eyes.

7.2 Requirements for a safe storage taking into consideration product incompatibilities

Requirements for storage areas and containers

Keep in the original containers and in a cool but frost-free and dry area.

Other information concerning storage

Protect from sunlight.

Information on storage incompatibilities

According to TRGS 510: Keep away from food and beverages.

Storage class: 3 Inflammable liquid chemicals (TRGS 510)

7.3 Specific end use(s)

No special terminal utilisation known with special handling or storage.



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8. Occupational Exposure Limits and Monitoring Personal Protection

8.1 Parameters to be monitored

Components with limit values that require monitoring at workplace

Components	CAS-Nr.	Value	Reference
Glutaral	111-30-8	AGW: 0,2 mg/m ³ , 0,05 ml/m ³ Top limit-exceedance factor: 2(l), Other indications: AGS, Sah, Y	TRGS 900

AGW = workplace limit, **AGS** = Committee on Hazardous Substances, **Y** = No need to fear foetal impairment with compliance of the AGW & BGW, Sah = Sensitization by skin contact or through the respiratory system possible. **Sah** = may cause respiratory and skin sensitization

DNEL (Derived No Effect Level) – Values:

Glutaral

Worker:

Short-term-Exposure - local effects, inhalation: 0,25 mg/m³

Glyoxal

Worker:

Long-term-Exposure - systemic effects, dermal: 48 mg/kg KG/day

Worker:

Long-term-Exposure - systemic effects, inhalation: 16,9 mg/m³

Isotridecanol, ethoxylated and didecyl dimethyl ammonium chloride

No data available

PNEC (Predicted No Effect Concentration) Values:

Glutaral

fresh water: 0,0025 mg/l

sewage treatment plant: 0,8 mg/l

ground: 0,03 mg/kg

sediment (sea water): 0,527 mg/kg

sediment (fresh water): 5,27 mg/kg

periodical release: 0,006 mg/l

sea water: 0,00025 mg/l

Glyoxal

fresh water: 0,319 mg/l

sewage treatment plant: 4,1 mg/l

ground: 4,06 mg/kg

sediment (sea water): 0,0685 mg/kg

sediment (fresh water): 0,685 mg/kg

periodical release: 1,1 mg/l

sea water: 0,0319 mg/l

Isotridecanol, ethoxylated and didecyl dimethyl ammonium chloride

No data available



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8.2 Limitation and Monitoring of the exposure

General protection - and hygienic measures

Keep concentrate away from foodstuffs, beverages and animal feed.
Remove immediately all clothing soiled or wet with the product (see 4.1).
Wash hands before breaks and at the end of the working shift. Avoid contact with eyes and skin.

Respiratory protection

In case of short-term handling of the concentrate (preparation of a use-solution) no protective respiratory equipment if the room ventilation is good.
Use dilutions in well ventilated areas only. In case of insufficient ventilation use a breathing apparatus with a multi-range protective ABEK filter.

Hand protection

Wear impervious gloves.
Wearing waterproof gloves for more than four hours on end daily can be seen as burdensome and should not be a permanent measure.

Penetration time of the glove material

The durability of gloves depends on a lot of particulars (material, layer thickness, manufacturer, temperature, stress time and duration) and is not predictable. Each user must test the resistance of the gloves for his particular assignment. The break-through time according to EN 374 must be specified by the manufacturer to allow for comparison of the gloves. See more detailed information in the German regulation: TRGS 401.

Recommendations

Gloves made of nitril or butyl rubber.

Skin protection

Protective work clothing.

To prevent occupational skin irritations it is recommended to proceed as follows independently from the actual contact to disinfectants:

- Apply a skin cream penetrating the skin rapidly whenever possible.
- Apply a slightly greasy skin-care cream on skin after washing the hands at the end of the working shift or before breaks.

Protection of eyes and face

Wear tight-fitting goggles when manipulating (for ex. when transfilling) the product.
If there is no danger of splashes, for ex. while applying the diluted product (disinfection of surfaces) it is not necessary to wear eye protection.

9. Physical and chemical properties

9.1 General information on the physical and chemical Properties

If no details are available on the product, relevant data can also be given for the components as follows: „Component: Details“.

Appearance	
- consistency:	liquid
- colour:	blue
Odour:	scented
Odour threshold:	Formaldehyde: 0,13 – 1,3 mg/m ³
pH (50 g/l H ₂ O) at 20 °C:	approximately 7

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Melting point:	not determined
Boiling point and boiling range:	not determined
Flash point:	53 °C (DIN 51755)
Evaporation velocity:	not determined
Flammability:	the product is not self-inflammable
Explosion limits in the air:	not applicable
Vapour pressure bei 20 °C:	not determined
Vapour density, relative (air =1):	not determined
Density at 20 °C:	1,05 g/cm ³
Water solubility:	completely soluble
Partition coefficient:	
n-Octanol/water:	not applicable for a mixture of substances
Autoignition temperature:	not determined
Decomposition temperature:	not applicable, no decomposition known
Viscosity:	not determined
Explosive properties:	the product as a liquid is not explosive
Oxidizing properties:	not determined

9.2 Other data

No other physical-chemical data were recorded.

10. Stability and Reactivity

10.1 Reactivity

No reactivity when used according to intended purpose.

10.2 Chemical stability

Stable under the recommended storage conditions and when used according to the intended purpose.

10.3 Possibility of hazardous reactions

No dangerous reactions if used according to the intended purpose.

10.4 Conditions to be avoided

See section 7.

10.5 Incompatible materials

Strongly oxidising agents.

10.6 Dangerous decomposition products

No decomposition when used as recommended.

11. Toxicological Data

11.1 Information about toxicological properties

The active substances have been extensively tested with regard to their toxic profile. The exposure does not induce any health hazards as long as they are handled properly. As far as the product is concerned there is no reason to expect any other results. For this reason the product was not tested



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in all toxicological categories. The data available on the dangerous substances/components has also to be taken into consideration.

11.1.1 For the product:

Acute toxicity

Oral application in SPF-wistar rats): LD₅₀ (24 h) = 1,69 ml/kg body weight; LD₅₀ (14 d) = 1,16 ml/kg body weight.

Dermal in rats: LD₅₀ (24 h) > 8,0 ml/kg- body weight; LD₅₀ (14 d) > 8,0 ml/kg body weight – non-toxic.

Inhalation according to OECD 403; fog / rats; 4 h exposure: LC₅₀ (14d) 6,0 µl/l – practically non-toxic.

Skin irritation / corrosion

Rats, undiluted: strong dermal irritations

Serious damage/irritation to eyes

OECD 405 in rabbits: at 1% → non irritant

Sensitization of the respiratory tract / skin

Sensitizing effect

Germ cell mutagenicity

No data available

Carcinogenic effects

No data available

Reproductive toxicity

No data available

Target organ effects – Toxicity after a single exposure

No data available

Target organ effects – Toxicity after repeated exposure

No data available

Aspiration hazard

No data available

Symptoms and effects (delayed and chronic) with description of the exposure route - As well as: Information about toxicokinetics, metabolism and distribution

No data available

11.1. For the following substances:

Glutaral

Acute Toxicity

Evaluation of the acute toxicity:

After short-term inhalation: high level toxicity. After swallowing a single dose: high level toxicity. Skin contact: minor toxicity.

Experimental/calculated data:

LD₅₀ in rats (oral): approx. 158 mg/kg (OECD guideline 401)

LC₅₀ in rats (inhalation): 0,48 mg/l 4 h (OECD guideline 403)–sprayed mist was tested.

LD₅₀ in rats (dermal): > 2.000 mg/kg (OECD guideline 402)

This data is based on the use of a diluted aqueous substance solution.

Irritation

Evaluation of the irritant effect:

Corrosive! Damages eyes and skin!

Experimental/calculated data:

Burns/irritation of the skin in rabbits: Corrosive (OECD guideline 404)

This data refers to a diluted aqueous substance solution.

Serious damage/irritation to the eyes in rabbits: Irreversible damage (Draize-Test)

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This data is based on the use of an aqueous solution of the substance.

Sensitization of respiratory tract / skin

Evaluation of the sensitization:

Skin sensitization may occur. Sensitization of the respiratory system may occur.

Experimental/calculated data:

Open epicutaneous test (OET). Guinea pigs: skin sensitizing.

This data refers to an aqueous solution of the substance.

Mutagenicity in germinative cells

Evaluation of the mutagenic effect:

Although the product showed a modification of the genetic material in bacteria and cell cultures in various test systems, this effect could not be confirmed by tests in mammals.

Carcinogenicity

Evaluation of the carcinogenic effect:

This substance showed no carcinogenic effect in animal long-term tests after ingestion of high concentrations in drinking water. This substance showed no carcinogenic effect in animals after long-term inhalation tests.

Reproductive toxicity

Evaluation of the reproductive toxicity:

Animal tests showed no indication that this substance might impair fertility.

Development toxicity

Evaluation of the teratogenic effect:

Animal tests showed no indication that this substance might cause developmental toxicity.

Specific Target Organ -Toxicity (single exposure)

Assessment STOT single:

On grounds of the available information an organ specific toxicity is not expected to occur.

Toxicity after repeated exposure and specific Target Organ-Toxicity (repeated exposure)

Assessment of the toxicity after repeated exposure:

After repeated exposure the main focus is still on the local irritation. Animal tests showed that repeated inhalation of the substance can damage the upper respiratory tract.

Other toxicological data:

The toxicological data is valid for the anhydrous substance

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Glyoxal (Data refers to 40% aqueous solution)

Acute Toxicity

Evaluation of the acute toxicity:

After swallowing a single dose: minor toxicity. After one single skin contact: practically not toxic.

After short-term inhalation: moderate toxicity.

Experimental/calculated data:

LD₅₀ in rats (oral): 2.000 – 5.000 mg/kg (OECD guideline 401)

LD₅₀ in rats (oral): 3.300 mg/kg (OECD guideline 401)

LC₅₀ in rats (inhalation): 2,44 mg/l 4 h (OECD guideline 403)

Spray-mist was tested.

LD₅₀ in rats (dermal): > 2.000 mg/kg (OECD guideline 402)

This data is based solely on the use of a limit concentration (LIMIT-Test).

Irritation

Evaluation of the irritant effect: Irritant to eyes by contact. EC-classification.

Can irritate the respiratory system.

Experimental/calculated data:

Burns/irritation of skin in rabbits: Irritant (OECD guideline 404)

Serious damage/irritation to eyes of rabbits: Irritant. (OECD guideline 405)

Sensitization of respiratory tract / skin

Evaluation of the sensitization:

Causes skin sensitization in tests in animals. Causes skin sensitization in human beings.

Experimental/calculated data:

Maximization-test in guinea pigs (GPMT): Skin sensitizing (OECD guideline 406)

Maximization-test in humans: skin sensitizing (source: Literature).

Mutagenicity in germinative cells

Evaluation of the mutagenic effect:

Although the product showed a modification of the genetic material in bacteria and cell cultures tested in various test systems, this effect could not be confirmed by tests in mammals.

A modification of the genetic material cannot be excluded on the grounds of experimental data.

Carcinogenicity

Evaluation of the carcinogenic effect:

This substance showed no carcinogenic effect in various tests for orientation purposes.

Reproductive toxicity

Evaluation of the reproductive toxicity:

Animal tests showed no indication that this substance might impair fertility.

Development toxicity

Evaluation of the teratogenic effect:

Animal tests showed no indication that this substance might cause developmental toxicity.

Specific Target Organ -Toxicity (single exposure)

Assessment STOT single: Irritation of the respiratory organs may occur.

Toxicity after repeated exposure and specific Target Organ-Toxicity (repeated exposure)

Assessment of the toxicity after repeated exposure:

After repeated exposure the main focus is still on the local irritation. Animal tests showed that repeated inhalation of the substance can damage the upper respiratory tract.

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According to inhalation tests in animals this substance can damage the upper respiratory organs after repeated exposure.

Aspiration hazard:
Not applicable

Didecyl dimethyl ammonium chloride

Acute oral toxicity
LD₅₀ = 238 mg/kg in rats – Method: OECD 401.

Acute dermal toxicity
LD₅₀ = 3342 mg/kg in rabbits.

Skin irritation
Irritant in rabbits – Exposure time: 3 min. Method: OECD 404

Sensitization
No sensitization in guinea pigs. Buehler test method: US-EPA

Gentoxicity in vitro:
Negative Ames Test in *Salmonella typhimurium* – Method: OECD 471
Negative Chromosome aberration Test: CHO cells
Negative Gene mutation, CHO Cells

Gene toxicity in vivo:
Negative Chromosome aberration Test oral in rats – Method: OECD 475

Isotridecanol, ethoxylated

The data given to the other substances is not relevant for this product.

12. Environmental Data

Some of the effects of the product were not tested. The data about the dangerous components have to be taken into consideration.

12.1 Toxicity Lysoformin 3000

Algal growth inhibition test following OECD with unicellular green alga:
LC₅₀ 96 h: 0,80 mg/l; LC₁₀ 96 h: 0,15 mg/l
Daphnia short-time test in accordance with OECD 202:
LC₅₀ 24 h: 0,3 mg/l
Rainbow trout / 96 h test:
LC₅₀ = 7,0 µg/l bath liquid

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Glutaral

Assessment of the aquatic toxicity:

Acutely toxic for the aquatic organisms. When introduced into biological treatment plants disturbances of the biodegradability of the activated sludge can take place depending on the local conditions and on the concentration of the product.

The raw material was not tested. This information was derived from data of a product or mixture with a lower substance concentration.

Fish toxicity:

LC₅₀ (96 h) 39 mg/l, *Cyprinodon variegatus* (acute fish test, static)

The data relative to the toxic effect is based on the nominal concentration.

LC₅₀ (96 h) 9,4 mg/l, *Lepomis macrochirus* (acute fish test, static)

The data relative to the toxic effect is based on the nominal concentration.

Aquatic Invertebrates:

EC₅₀ (48 h) 5,75 mg/l, *Daphnia magna* (acute daphnia test, static)

The data relative to the toxic effect is based on the nominal concentration

EC₅₀ (96 h) 0,75 mg/l, *Crassostrea virginica* (other, flow-through)

The data relative to the toxic effect is based on the analytically determined concentration.

LC₅₀ (96 h) 5,5 mg/l, *Mysidopsis bahia* (OPP 72-3 (EPA-Directive), flow-through)

The data relative to the toxic effect is based on the analytically determined concentration.

Aquatic plants:

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

The data relative to the toxic effect is based on the analytically determined concentration.

EC₅₀ (72 h) 0,92 mg/l (growth rate), *Skeletonema costatum* (ISO/DIS 10253)

The data relative to the toxic effect is based on the nominal concentration.

Micro-organisms/Effect on the activated sludge:

EC₂₀ (30 min) approximately 15 mg/l, activated sludge, communal (OECD guideline 209, aerobic).

The data relative to the toxic effect is based on the nominal concentration.

Chronic Toxicity Fish:

NOEC (97 d) 1,6 mg/l, *Oncorhynchus mykiss*

The data relative to the toxic effect is based on the nominal concentration.

Chronic Toxicity of aquat. Invertebrates:

NOEC (21 d), 2,5 mg/l, *Daphnia magna* (OECD guideline 202, semistatic)

The data relative to the toxic effect is based on the analytically determined concentration.

Terrestrial plants:

EC₂₀ (19 d) > 450 mg/kg, *Vicia sativa* (OECD guideline 208)

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Glyoxal (Data refers to 40% aqueous solution)

Assessment of the aquatic toxicity:

It is highly probable that this substance is not acutely harmful for the aquatic organisms. When introduced into biological treatment plants in small quantities disturbances of the biodegradability of the activated sludge are not to be expected.

Fish toxicity:

LC₅₀ (96 h) 460 - 680 mg/l, *Leuciscus idus* (DIN 38412 Part 15, static) nominal concentration.

Aquatic Invertebrates:

EC₅₀ (48 h) 404 mg/l, *Daphnia magna* (Directive 79/831/EEC, static) nominal concentration

Aquatic plants (substance glyoxal):

EC₅₀ (72 h) > 100 mg Glyoxal/l (growth rate), *Scenedesmus subspicatus* (OECD guideline 201, static) nominal concentration

Micro-organisms/Effect on the activated sludge:

EC₂₀ (0,5 h) > 1.000 mg/l, activated sludge (OECD guideline 209, static).

Chronic Toxicity Fish:

NOEC (34 d) 112 mg/l, *Pimephales promelas* (OPP 72-4 (EPA Directive) flow-through)

Chronic Toxicity of aquat. Invertebrates:

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

Ground existing organisms (substance Glyoxal):

LC₅₀ (14 d) > 398 mg/kg, *Eisenia foetida* (OECD guideline 207, artificial soil test)

Other tests (28 d > 400 mg/kg, ground-micro-organisms (OECD 217)

The data on the toxic effect is based on the nominal concentration.

Other tests (28 d > 400 mg/kg, ground-micro-organisms (OECD 216)

The data on the toxic effect is based on the nominal concentration

Terrestrial plants (substance Glyoxal):

NOEC (21 d), *Brassica napus* (OECD guideline 208)

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Didecyl dimethyl ammonium chloride

Toxicity for fish:

LC₅₀ = 0,19 mg/l in *Pimephales promelas*, Exposure time: 96 h; Method: US-EPA
NOEC: 0,032 mg/l bei *Danio rerio*, chronic toxicity, exposure time: 34 d with OECD 210

Toxicity for daphnia:

EC₅₀ 0,062 mg/l, *Daphnia magna*, immobilisation, exposure time : 48 h, method : EPA-FIFRA
NOEC :
0,010 mg/l, *Daphnia magna*, reproduction test, exposure time: 21 d; method: OECD 211,

Toxicity for algae :

ErC₅₀: 0,026 mg/l, *Pseudokirchneriella subcapitata* (green algae), growth inhibition,
exposure time: 96 h; method: OECD 201

Toxicity for bacteria :

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

Toxicity for soil organisms

NOEC: ≥ 1000 mg/kg, *Eisenia fetida* (rain worms), acute toxicity, exposure time: 14 d; method:
OECD 207

Toxicity for terrestrial organisms:

EC₅₀ : 283 - 1670 mg/kg, exposure time: 14 d; method: OECD 208

Behaviour in environmental compartments: mobility in soil, method US-EPA

Isotridecanol, ethoxylated

Toxicity for fish

Isotridecanol, ethoxilated (8 - 15 EO): LC₅₀ (96 h), *Cyprinus carpio* (carps): 1 – 10 mg/l
Flow-through test; OECD-test procedure 203, own test results / literature – Group consideration

Toxicity for daphnia and other aquatic invertebrates:

Isotridecanol, ethoxilated (8 - 15 EO):
EC₅₀ (48 h) *Daphnia magna* (big water flea) : 1 – 10 mg/l ; static test ; OECD-test procedure 202,
own test results/values from literature group consideration

Toxicity for aquatic plants:

Isotridecanol, ethoxilated (8 - 15 EO):
EC₅₀ (72 h) *Desmodesmus subspicatus* (green algae): 1 – 10 mg/l ; static test ; OECD-test
procedure 201, own test results/values from literature group consideration

Toxicity of Isotridecanol, ethoxylated (8 – 15 EO) for bacteria:

EC₅₀ activated sludge: 140 mg/l; respiration Inhibition group consideration (literature)

Ground existing organisms:

Isotridecanol, ethoxilated (8 - 15 EO):
NOEC *Eisenia foetida*: 220 mg/kg: artificial soil test group consideration (literature)

Toxicity for terrestrial plants:

Isotridecanol, ethoxilated (8 - 15 EO):
Development, growth; NOEC: 10 mg/kg, *Lepidium sativum* (cress); OECD-test guidelines 208
Own test results/literature group consideration



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12.2 Persistence and biological degradability

Product

DIN 38412 Part 25: 90% within 17 days; corresponds to "easily biodegradable".

Glutaral

Assessment of the biological degradability and elimination (H₂O):

Easily biodegradable (according to the OECD-criteria).

Details about the elimination:

90 - 100 % DOC-reduction (28 d) (OECD 301 A (new Version) (aerobic, activated sludge, communal)

Easily biodegradable (according to the OECD-criteria).

Assessment of the stability in water:

Degrades slowly by reaction with water.

Stability in water (hydrolysis):

$t_{1/2} > 1$ a (50 °C), (Directive 92/69/EWG, C.7, pH7)

Substance degrades slowly by reaction with water.

Glyoxal (data refers to 40% aqueous solution)

Assessment of the biological degradability and elimination (H₂O):

Easily biodegradable (according to the OECD-criteria).

Details about the elimination:

90 - 100 % DOC-reduction (19 d) (OECD 301 A (new Version) (aerobic, activated sludge, communal, not adapted). Easily biodegradable (according to the OECD-criteria).

Assessment of stability in water:

Because of the structure hydrolyse is not to be expected.

Didecyl dimethyl ammonium chloride

Stability in water: Abiotic degradation, hydrolytic stable, method: EPA-FIFRA

Biological degradability

Modified Sturm test: 72%, easily biologically degradable, test period: 28 d, method: OECD 301 B

Die-Away Test: 93,3 %, test period: 28 d

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

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

Isotridecanol

biological degradability:

Branched-chain Alcohols C13, ethoxylated (6-9 EO):

Biodegradable, > 60 %; 60 d; anaerobic biodegradation – own results/literature – group consideration

biological degradability:

Isotridecanol, ethoxylated (8 – 15 EO):

Easily biodegradable; > 60%; 28 d; aerobic; OECD TG 301 B – own results/Literature – group consideration



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12.3 Bioaccumulation potential

Glutaral

Assessment of the bioaccumulation potential:

Because of the n-octanol/water distribution coefficient (log Pow) a noteworthy accumulation in organisms is not to be expected.

Glyoxal (data refers to 40% aqueous solution)

Assessment of the bioaccumulation potential:

A noteworthy accumulation in organisms is not to be expected.

Bioaccumulation potential:

Bioconcentration factor: 3,2 (calculated)

Didecyl dimethyl ammonium chloride

No data available

Isotridecanol

Isotridecanol,ethoxylated (8 – 15 EO): Bioaccumulation is unlikely (literature).

12.4 Mobility in the soil

Glutaral

Assessment of the transport between the environment compartments:

The substance does not evaporate in the atmosphere from the surface of the water.

A bonding to the solid soil phase is possible.

Glyoxal

Assessment of the transport between the environment compartments:

The substance does not evaporate in the atmosphere from the surface of the water.

A bonding to the solid soil phase is not to be expected.

Didecyl dimethyl ammonium chloride

No data available

Isotridecanol

Isotridecanol,ethoxylated (8 – 15 EO):

Koc: > 5000 immobile strong adsorption on the soil (literature)

12.5 Result of the PBT- and vPvB-Assessments

The product contains no chemicals which can be classified as PBT- or vPvB-substances.

12.6 Other adverse effects

The water pollution hazard class 3 (according to VwVwS) was allocated to this product.

Safety Data Sheet
according to Regulation (EG) no. 1907/2006



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13. Disposal Considerations

13.1 Handling method for the elimination of the product

Handling of the product

May be disposed of according to the local regulation, for ex. in an appropriate waste disposal site or incineration plant. Do not dispose of it into the public sewage system.

Handling of the used packaging

Empty packages can be discarded in the recycling containers (for ex. yellow containers).

Waste code according to the ordinance on Waste Materials Catalogues (AVV)

07 06 04 other organic solvents, washing liquids and mother liquors
15 01 02 Packages made of plastic materials

Relevant EU- and other Regulations

TRGS 201 (Labelling of the Chemical Wastes), KrW-/AbfG (Cycle and Waste Management Act)

14. Transport

14.1 UN-Number

2924

14.2 UN proper shipping name

All types of transport:
2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (glutaral, didecyl dimethyl ammonium chloride)

14.3 Transport hazard classes

Road: ADR/RID and GGVS/GGVE Class: 3 flammable liquid
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 risk

Characterisation of the environmental hazardous substances

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

IMDG-Code: Marine Pollutant: yes / no

14.6 Special precautions for the user (forwarding agent)

None

14.7 Bulk transport according to Annex II of the MARPOL-Agreement 73/78 and according to the IBC-Code

No bulk transport

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15. Regulatory Information

15.1 Safety, health and environmental regulations / Legislation specific for the product

EC Regulations:

1907/2006 REACH / 1272/2008 CLP GHS / 1999/45/EG Dangerous mixtures (until June 2015) / 98/24/EG Hazards due to exposure to dangerous chemical substances / 648/2004 Detergents regulation

German Regulation:

Chemicals act ChemG / German ordinance on hazardous substances GefStoffV / TRGS and Announcements / Regulation for industrial safety BetrSichV / Young persons protection of employment Act / Law on maternity protection / Professional association's and trade inspectorate's guidelines

Other regulations, restriction and prohibition ordinances:

Medical device class IIa CE 0482 according to the German law on medical devices
Biocide: Baua Reg.-No. N-12657, N-12658, N-12659

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this mixture.

16. Other Information

Changes made in this version in comparison to the last one:

Completely revised edition - New format according to the legal ordinance (EC) No.453/2010
Important modifications: Section 7.2 storage class

Bibliographical references and data sources

TRGS / GESTIS-Substance Data Base / Occupational Assurance Associations / Safety Data Sheet of the components

Methods according to Article 9 of the legal ordinance (EC) No.1272/2008 for the evaluation of the informations for the classification of the chemical substances:

The classification was carried out according to 1999/45/EC

Wording of the hazard statement, R-phrases in accordance with Section 3:

According to Directive 67/548/EWG:

R-Phrases:

20	Harmful by inhalation
22	Harmful if swallowed
23/25	Toxic by inhalation and if swallowed
34	Causes burns
36	Irritating to eyes
37	Irritating to respiratory system
38	Irritating to skin
41	Risk of serious damage to eyes
42/43	May cause sensitization by inhalation and skin contact
50	Very toxic to aquatic organisms
68	Possible risk of irreversible effects

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According to legal ordinance (EG) No. 1272/2008 (CLP / GHS):

Hazard warnings (H-phrases):

H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritations
H331	Toxic if inhaled
H332	Harmful if inhaled
H334	May cause allergy, asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H400	Very toxic to aquatic life

The information contained in this safety data sheet is based on the present state of our knowledge and experience and describes the product with regard to the security requirements for a safe use of this product. This data is definitely not a description of the product itself (product specification). A description of the product or its suitability for a particular application cannot be derived from the data given in the safety data sheet. We will be glad to give you advice on the question whether a product is suitable for a specific use and under which conditions.
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