

Safety Data Sheet

according to Regulation (EG) no. 1907/2006



Revision date : 05.07.2013
Coming in force: 12.07.2013

Version: 6
replaces version: 5

Lysoformin[®] 2000 / Aldosan(e) (CH)

1. Product and Company Identification

1.1 Product information

Trade name: Lysoformin[®] 2000 / Aldosan(e) (CH)

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

Applications of the product

Disinfection by wiping or immersion/soaking also for medical devices.
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: 145 / only within Switzerland
Telefax: 0041 44 2528833

2. Hazard Identification

2.1 Classification of the substance or product

According to Directive 1999/45/EG:

Xn; R 20/21/22; R 37/38; R 40; R 41; R 42/43; R 68

2.2 Labelling:

According to Directive 1999/45/EG:

Danger symbol:



Xn

Hazard warnings:

R68/20/21/22 Harmful: possible risk of irreversible damage through inhalation, in contact with skin and if swallowed.

R 37/38 Irritating to respiratory system and skin.

R 40 Limited evidence of carcinogenic effect.

R 41 Risk of serious damage to eyes.

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R 42/43 May cause sensitization by inhalation and skin contact.

Safety considerations:

- S 2 Keep out of the reach of children.
- S 26 In case of contact with eyes rinse immediately with plenty of water and seek medical advice.
- S 28 After contact with skin, wash immediately with plenty of water
- 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.
- S35 This material and its container must be disposed of in a safe way.

Hazard determining components for labelling

Formaldehyde, Glutaral and Glyoxal

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:

Formaldehyde

EC-No.: 200-001-8 CAS-No.: 50-00-0 REACH-Registration No.: 01-2119488953-20

Proportion: 13,0 %

Classification according to directive 67/548/EC:

Carcinogenicity Cat. 3, T, C R40-23/24/25-34-43

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

Carcinogenicity: Category: 2 H351

Acute toxicity: Cat. 3 H301: H311; H331

Burns or irritation of the skin: Cat. 1B H314

Sensitization of skin: Cat. 1 H317

Glutaral

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

Proportion: 3,2 %

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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:

Substance or product corrosive to metals: Category 1 H290

Acute toxicity (oral): Cat. 3 H301

Acute toxicity (inhalation - mist): Cat. 3 H331

Burns or irritation on skin: Cat. 1B H314

Sensitization of respiratory system: Cat. 1 H334

Sensitization of skin: Cat. 1 H317

Acute hazard to the aquatic environment: Cat. 1 H400

Chronic hazard to the aquatic environment: Cat 2 H411

Glyoxal

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

Proportion : 3,6 %

Classification according to directive 67/548/EWG:

Xn; R 20-36/37/38-43-68

Classification according to ordinance (EG) Nr. 1272/2008:

Acute toxicity (inhalation - mist): Cat. 4 H332

Corrosive/irritant to skin: Cat. 2 H315

Skin sensitization: Cat. 1 H317

Severe damage or irritation to eyes: Cat. 2 H319

Germ cell mutagenicity: Cat.2 H341

Specific target organ toxicity (after single exposure): Cat. 3 (irritating to respiratory system) H335

Alkylether sulfate C12-14 with 2 mol EO, Sodium salt

EC-No.: 500-234-8 CAS-No.: 68891-38-3 REACH-Registration No.: 01-2119488639-16

Proportion: < 5 %

Classification according to Directive 67/548/EC:

Xi; R 38-41

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

Irritation to skin: Cat. 2 H315

Severe damage to eyes: Cat. 1 H318

Chronic hazard to the aquatic environment: Cat 3 H412

Isotridecanol, ethoxylated

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

Proportion: < 5 %

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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 damage to eyes: Cat. 1 H318

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

Anionic surfactants < 5 %
Non-ionic surfactants ... < 5 %

Fragrances (BENZYL SALICYLATE, COUMARIN, LINALOOL)

(Wording of R-phrases and hazard statements: See Section 16)

4. First Aid Measures

4.1 Description of the First Aid Measures

General information:

Seek medical advice immediately and show safety data sheet, packaging 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 running water with the eyelid held wide open for 10 minutes.

Seek medical advice immediately after rinsing.

After swallowing:

Do not induce vomiting. Rinse mouth with water, and then drink plenty of water.

4.2 Most important symptoms and effects appearing immediately or later

Irritation of the mucous membranes, headache, unwell feeling.

4.3 Medical first aid or special treatments

Information for the doctor:

Therapy like for chemical burns.

5. Firefighting Measures

5.1 Extinguishing media

Suitable extinguishing media:

Water jet, carbon dioxide, extinguishing powder, 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

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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.

6. Accidental Release Measures

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

Wear adequate protective gloves and clothes and respiratory equipment. 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 there are no puddles left on the ground. Tightly close containers after use. To prepare the use dilutions always fill up container with water first and then add the product.

General hygienic measures at workplace:

Wash hands before break 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: 12 Non-flammable liquid (TRGS 510)

7.3 Specific end use(s)

No special terminal utilization 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
Formaldehyde	50-00-0	AGW inoperative (currently in the assessment phase) MAK: 0,37 mg/m ³ , 0,3 ml/m ³ Top limit-exceedance factor: 2 (1);	MAK of 2000
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, **MAK** = Maximum workplace concentration, **AGS** = Committee on Hazardous Substances, **Y** = No need to fear foetal impairment with compliance of the AGW & BGW.
Sah = May cause sensitization by contact with skin or respiratory system.

DNEL (Derived No Effect Level) - Values:

Formaldehyde

Worker:

Long-term-Exposure - systemic effects, dermal: 240 mg/kg

Worker:

Long-term-Exposure - systemic and local effects, inhalation: 0,5 mg/m³

Worker:

Short-term-Exposure – systemic and local effects, inhalation: 1 mg/m³

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

Alkylether sulfate

Worker:

Long-term-Exposure - systemic effects, dermal: 2750 mg/m³

Long-term-Exposure - systemic effects, inhalation: 175 mg/m³

Isotridecanol, ethoxylated

No data available

PNEC (Predicted No Effect Concentration) - Values:

Formaldehyde

fresh water: 0,47 mg/l

sewage treatment plant: 0,19 mg/l

ground: 0,21 mg/l

sediment (sea water): 2,44 mg/l

sediment (fresh water): 2,44 mg/l

periodical release: 4,7 mg/l

sea water: 0,47 mg/l

Glutaral

fresh water: 0,0025 mg/l

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

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sewage treatment plant: 0,8 mg/l
ground: 0,03 mg/kg
sediment (sea water): 0,527 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

Alkylether sulfate

fresh water: 0,24 mg/l
sewage treatment plant: 10000 mg/l
ground: 0,946 mg/kg
sediment (sea water): 0,545 mg/kg

sediment (fresh water): 5,45 mg/kg
periodical release: 0,071 mg/l
sea water: 0,024 mg/l

Isotridecanol, ethoxylated

No data available

8.2 Limitation and Monitoring of the Exposure

Individual protective measures - personal protective equipment:

General protection - and hygienic measures

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

Respiratory protection

In case of short-term handling of the concentrate (preparation of a solution) no protective respiratory equipment if the room ventilation is good. Prepare use dilutions only in well ventilated areas. 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, butyl rubber.

Skin protection

Protective clothing at workplace.

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. transferring) the product.

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If there is no danger of splashes, protection while applying the diluted product (disinfection of surfaces) is not necessary.

9. Physical and chemical properties

9.1 General information on the physical and chemical Properties

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

Appearance	
- consistency:	liquid
- colour:	blue
Odour:	characteristic
Odour threshold:	formaldehyde: 0,13 – 1,3 mg/m ³
pH (50 g/l H ₂ O) at 20 °C:	approx. 7
Melting point:	not determined
Boiling point and boiling range:	not determined
Flash point:	> 70 °C (DIN 51755, open skillet)
Evaporation velocity:	not determined
Flammability:	the product is not spontaneously self-inflammable
Explosion limits in the air:	not applicable
Vapour pressure:	Not determined
Vapour density, relative (air =1):	Not determined
Density at 20 °C:	approx. 1,1 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 represents no explosion hazard
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 the intended use.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No dangerous reactions if used according to the intended use.

10.4 Conditions to be avoided

See Section 7.



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10.5 Incompatible materials

Strongly oxidizing agents, acids and bases.

10.6 Dangerous decomposition products

No decomposition when used as recommended.

11. Toxicological Data

11.1 Information about toxicological properties

The toxicological profile of the active substances has been intensively investigated. Exposure is safe as long as they are stored and handled correctly. Considering the mixture no other result is to be expected. Therefore the product has not been tested with regard to all categories of possible toxic effects. The data available on the dangerous substances/components has also to be taken into consideration.

11.1.1 Product:

Acute toxicity

Inhalation: LC₅₀ after 24 h = 27 ml/h over 4 h; LC₅₀ after 14d = 16 ml/h over 4 h (rats) practically non-toxic.

Oral: LD₅₀ = 1,82 – 2,49 ml/kg body weight (rats)

Skin irritation / corrosion

No data available.

Serious damage/irritation to eyes

No data available

Sensitization of the respiratory tract / skin

No data available

Germ cell mutagenicity

No data available

Carcinogenic effects

No data available

Reproductive toxicity

No data available

Specific Target organ effects – Toxicity after a single exposure

No data available

Specific 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

11.1.2 For the following substances:

Formaldehyde

Acute Toxicity

Toxic: serious danger of irreversible damage by inhaling, skin contact and by swallowing.

Acute oral toxicity LD₅₀ 600 – 800 mg/kg in rats.

Acute dermal toxicity LD₅₀ 270 mg/kg in rabbits.

Irritative and corrosive effect

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Causes burns/irritations.
Irritates the respiratory system.

Sensitization effects

May cause sensitization by skin contact.

Carcinogenicity, mutagenicity and reproduction toxicity

Suspected hazard of carcinogenic effect:

Further information about the testing

Formaldehyde vapours are harmful to human health at a concentration of less than 1 ppm in the air when inhaled and cause irritations of the eyes and of the respiratory system. Aqueous solutions cause irritations or burns to eyes, skin and mucous membranes, depending on their concentration.

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 used.

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)

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.

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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 after a single exposition to the substance.

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.

Glyoxal (Data refer to a 40% aqueous solution)

Acute Toxicity

Evaluation of the acute toxicity:

After swallowing a single dosis: 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) – aerosol spray 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 trials 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.

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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:

Can have an irritant effect on the respiratory system.

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

Assessment of the toxicity after repeated exposure:

Animal tests showed that repeated inhalation of the substance can damage the upper respiratory tract.

Aspiration hazard:

Not applicable.

Alkylether sulfate and Isotridecanol, ethoxylated

The data for these substances are 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 2000

Daphnia short-time test:

LC₅₀ 24h: 243 mg/l slope factor 1.36 / LC₁₀₀ = 450 mg/l LC₀ = 50 mg/l

Rainbow trout 96 h test:

LC₅₀ = 0.048 mg/l bath liquid

Formaldehyde

LC₅₀ Sunfisch: 6.7 mg/l 96 h formaldehyde

EC₅₀ Daphia magna: 42 mg/l 24 h formaldehyde

EC₁₀ Pseudomonas putida : 14 mg/l 16 h formaldehyde

Assessment of the aquatic toxicity:

Acute fish toxicity: LC₅₀ 41 mg/l Brachydanio rerio 96 h

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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)

NOEC (72 h) 0,025 mg/l, *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 aquatic invertebrates:

NOEC (21 d) 2.5 mg/l *Daphnia magna* (OECD guideline 202, Part 2, semistatic)

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

Terrestrial plants:

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

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.

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Aquatic invertebrates:

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

Aquatic plants (refers to the substance Glyoxal):

EC₅₀ (72 h) > 100 mg/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 (refers to the 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 (refers to the substance Glyoxal):

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

Alkylether sulphate (data refers to the aqueous solution of max 30%)

Acute fish toxicity:

LC₅₀ 10 - 100 mg/l, Leuciscus idus, Method: ISO 7346/2.

GHS: Category 3 (not implemented in the EU)

Acute Aquatic invertebrates:

EC₅₀ 10 - 100 mg/l Method: OECD 202 Part 1.

Aquatic plants:

EC₅₀ > 100 mg/l, Scenedesmus subspicatus – Test method: OECD 201

Acute bacteria toxicity:

EC₀ > 100 mg/l, Pseudomonas putida – Test method: OECD 209

Chronic fish toxicity:

NOEC > 1 - <= 10 mg/l, Leuciscus idus

Chronic invertebrates toxicity:

NOEC > 1 - 10 mg/l, Daphnia magna

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Lysoformin[®] 2000 / Aldosan(e) (CH)

Isotridecanol, ethoxylated

Fish toxicity:

Isotridecanol, ethoxylated, (8 - 15 EO) LC₅₀ (96 h) cyprinus carpio (carps): 1 - 10 mg/l; flow-through test; OECD test guideline 203, own external test results/literature. Group contemplation

Toxicity for daphnia and other aquatic invertebrates of Isotridecanol, ethoxylated, (8 – 15 EO):
EC₅₀ (48 h) daphnia magna (big water flea): 1 – 10 mg/l; static test; OECD guideline 202, own test results/literature. Group contemplation

Toxicity for aquatic plants

Isotridecanol, ethoxylated (8-15 EO):

EC₅₀ (72 h) desmodesmus subspicatus (green algae): 1 – 10 mg/l; static test; OECD test guideline 201; Own test results/values from literature. Group contemplation

Toxicity on bacteria / Isotridecanol, ethoxylated (8-15 EO):

EC₅₀ activated sludge: 140 mg/l; inhibition of respiration - Group contemplation (value from literature)

Toxicity on ground existing organisms

Isotridecanol, ethoxylated (8-15 EO):

NOEC eisenia foetida: 220 mg/kg, artificial soil test – Group contemplation (value from literature)

Toxicity for terrestrial plants

Isotridecanol, ethoxylated (8-15 EO):

Accumulation, growth; NOEC: 10 mg/kg; lepidium sativum (cress); OECD test guideline 208);
Own test results/Value from literature - Group contemplation

12.2 Persistence and biological degradability

Formaldehyde

According to the OECD criteria the substance is easily biodegradable (readily 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.

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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:

Hydrolyse is not to be expected because of the structure

Alkylether sulphate (data refers to the aqueous solution of max 30%)

Assessment of biodegradation and elimination (H₂O)

Easily biodegradable (according to the OECD criteria).

Elimination:

(Annex III, Part A) The surfactant contained in this product meets the conditions of the biological degradation as set in the Guideline (EC) No.648/2004 for detergents. Documents which confirm this assertion must be held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

Isotridecanol, ethoxylated

Biological degradability:

Alcohols C13 branches of, ethoxylated (6-9 EO):

Biologically degradable; > 60%; 60 d; anaerobic biodegradation own test results/values from literature - Group contemplation

Biological degradability:

Isotridecanol, ethoxylated 8-15 EO):

Readily biologically degradable; > 60%; 28 d; aerobic; OECD TG 301 B own test results/values from literature - Group contemplation

12.3 Bioaccumulation potential

Formaldehyde

Given the low log Po/w it can be assumed that bioaccumulation potential is low.

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.

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Lysoformin[®] 2000 / Aldosan(e) (CH)

Glyoxal (data refers to the 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)

Alkylether sulphate (data refers to the aqueous solution of max 30%)

Assessment of the bioaccumulation potential:

An accumulation in the organisms is not to be expected.

Isotridecanol, ethoxylated

Isotridecanol, ethoxylated (8–15 EO):

Bioaccumulation improbable (literature)

12.4 Mobility in the soil

Formaldehyde

High mobility in 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.

Alkylether sulphate (data refers to the aqueous solution of max 30%)

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.

Isotridecanol, ethoxylated

Isotridecanol, ethoxylated (8-15 EO):

Koc: > 5.000 immobile strong Adsorption on ground (literature value)

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.

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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

Emptied packages can be discarded in recycling (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

1903

14.2 UN proper shipping name

All types of transport:

1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (glutaral, formaldehyde)

14.3 Transport hazard classes

Road: ADR/RID and GGVS/GGVE Class: 8 Corrosive materials
Tunnel restriction code: E

Sea: IMDG/GGV Sea-Class: 8
EMS-number: F-A, S-B

Air: ICAO-TI / IATA-DGR-class: 8

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-12653, N-12654

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this mixture.

16. Other Information

Modifications compared to the previous version

Version 5: Completely revised edition - New format according to the legal ordinance (EU) Nr. 453/2010

Version 6: Title / 1.1 and 1.4 Emergency Tel.-No / Section 16 Additional R- and H sentences / Section 11; 12 and 3.2 Data relative to Alkyl ether sulphate / Section 12.1 and 3.2 Glutaral (H411)

Bibliographical references and data sources

TRGS 510 / GESTIS-Substance Data Base / Occupational Assurance Associations / Safety Data Sheet of the components

Methods according to Article 9 of the legal ordinance (EG) 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/EG

Wording of the hazard statement, and of the relevant risk-phrases (R-phrases) in accordance with Section 3:

According to Directive 67/548/EWG:

R-Phrases:

- | | |
|----|-----------------------------------|
| 10 | Flammable. |
| 11 | Highly inflammable. |
| 20 | Harmful by inhalation. |
| 22 | Harmful if swallowed. |
| 23 | Toxic by inhalation. |
| 24 | Toxic by skin contact. |
| 25 | Toxic if swallowed. |
| 34 | Causes burns. |
| 36 | Irritating to eyes. |
| 37 | Irritating to respiratory system. |
| 38 | Irritating to skin. |

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- 40 Limited evidence of a carcinogenic effect.
- 41 Risk of serious damage to eyes.
- 42/43 May cause sensitization by inhalation and skin contact.
- 50 Very toxic to aquatic organisms.
- 66 Repeated exposure may cause skin dryness or cracking.
- 67 Vapours may cause dizziness and drowsiness.
- 68 Possible risk of irreversible effects.

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

Hazard warnings:

- H225 Highly flammable liquid and vapours.
- H290 May be corrosive to metals.
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H311 Toxic in contact with skin.
- 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 or asthma symptoms or breathing difficulties if inhaled.
- H335 May cause respiratory irritation.
- H336 May cause drowsiness or dizziness.
- H341 Suspected of causing genetic defects.
- H351 Suspected of causing cancer.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.
- EUH066 Repeated exposure may cause skin dryness or cracking.

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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