

# Safety data sheet

## according to 1907/2006/EC, Article 31

Printing date 14.06.2021

Version number 3

Revision: 08.06.2021

- **1.1 Product identifier**
- **Trade name:** SunSept Instrumentendesinfektion PREMIUM HIGH Konz.
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Life cycle stages PW** Widespread use by professional workers
- **Sector of Use SU20** Health services
- **Product category PC8** Biocidal products
- **Technical function** Biocide
- **Application of the substance / the mixture** Disinfectants for instruments
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
PRISMAN GmbH  
Otto Hahn Ring 6-18  
D-64653 Lorsch  
Germany
- **Further information obtainable from:**  
Abteilung Produktsicherheit  
Alexander.Metz@prisman.de
- **1.4 Emergency telephone number:** ++49 (0)6251 866980-0, Mo - Fr 8-18 Uhr

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
- Acute Tox. 4     H302 Harmful if swallowed.
- Skin Irrit. 2     H315 Causes skin irritation.
- Eye Dam. 1     H318 Causes serious eye damage.
- 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.
- STOT SE 3     H335 May cause respiratory irritation.
- Aquatic Acute 1     H400 Very toxic to aquatic life.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05    GHS07    GHS08    GHS09

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
glutaral  
(Ethylendioxy)dimethanol  
N,N-Dimethyl-N-Dioctylammoniumchlorid  
Fettalkoholpolyglykolether
- **Hazard statements**  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H318 Causes serious eye damage.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H317 May cause an allergic skin reaction.  
H335 May cause respiratory irritation.  
H400 Very toxic to aquatic life.
- **Precautionary statements**  
P261                    Avoid breathing mist/vapours/spray.  
P280                    Wear protective gloves / eye protection / face protection.

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- P284 [In case of inadequate ventilation] wear respiratory protection.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P310 Immediately call a POISON CENTER/doctor.  
 P321 Specific treatment (see on this label).  
 P330 Rinse mouth.  
 P362+P364 Take off contaminated clothing and wash it before reuse.  
 P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.  
 P405 Store locked up.
- **Labelling of packages where the contents do not exceed 125 ml -**
  - **2.3 Other hazards**
  - **Results of PBT and vPvB assessment**
  - **PBT:** Not applicable.
  - **vPvB:** Not applicable.

### SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

|   |  |         |
|---|--|---------|
| CAS: 3586-55-8<br>EINECS: 222-720-6   | (Ethylendioxy)dimethanol<br>⚠ Acute Tox. 4, H302   | 10-25%  |
| CAS: 111-30-8<br>EINECS: 203-856-5<br>Index number: 605-022-00-X<br>RTECS: MA 2450000 | glutaral<br>⚠ Acute Tox. 3, H301; Acute Tox. 2, H330; ⚠ Resp. Sens. 1, H334; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 2, H411; ⚠ Skin Sens. 1A, H317; STOT SE 3, H335<br>Specific concentration limit: STOT SE 3; H335: C ≥ 0.5 % | 2.5-10% |
| CAS: 5538-94-3  | N,N-Dimethyl-N-Dioctylammoniumchlorid<br>⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410   | ≤2.5%   |
| CAS: 26183-52-8   | Fettalkoholpolyglykoether<br>⚠ Eye Dam. 1, H318  | ≤2.5%   |
| CAS: 111-90-0<br>EINECS: 203-919-7<br>RTECS: KK 8750000                               | Diethylene glycol monoethyl ether  | 2.5-10% |

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**  
Immediately remove any clothing soiled by the product.  
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**  
Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** Call for a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

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**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Use neutralising agent.  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.

· **Ingredients with limit values that require monitoring at the workplace:**

**111-30-8 glutaral**

|     |  |
|-----|--|
| WEL | Short-term value: 0.2 mg/m <sup>3</sup> , 0.05 ppm |
|     | Long-term value: 0.2 mg/m <sup>3</sup> , 0.05 ppm  |
| Sen |  |

- **Additional information:** The lists valid during the making were used as basis.

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### · 8.2 Exposure controls

#### · Personal protective equipment:

#### · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

#### · Respiratory protection:

Not necessary if room is well-ventilated.

Not required.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

#### · Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

#### · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

#### · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

#### · For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Rubber gloves

#### · For the permanent contact gloves made of the following materials are suitable: Neoprene gloves

#### · As protection from splashes gloves made of the following materials are suitable:

Fluorocarbon rubber (Viton)

Rubber gloves

#### · Eye protection:



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

#### · General Information

#### · Appearance:

Form: Liquid

Colour: Clear

· Odour: Pungent

· Odour threshold: Not determined.

· pH-value at 20 °C: 4.5

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|  |   |
|--|---|
| · <b>Change in condition</b>                     |   |
| Melting point/freezing point:                    | Undetermined.                                 |
| Initial boiling point and boiling range:         | 100 °C  |
| · <b>Flash point:</b>                            | Not applicable.                               |
| · <b>Flammability (solid, gas):</b>              | Not applicable.                               |
| · <b>Decomposition temperature:</b>              | Not determined.                               |
| · <b>Auto-ignition temperature:</b>              | Product is not selfigniting.                  |
| · <b>Explosive properties:</b>                   | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                       |   |
| Lower:   | Not determined.                               |
| Upper:   | Not determined.                               |
| · <b>Vapour pressure at 20 °C:</b>               | 23 hPa  |
| · <b>Density at 20 °C:</b>                       | 1 g/cm <sup>3</sup>                           |
| · <b>Relative density</b>                        | Not determined.                               |
| · <b>Vapour density</b>                          | Not determined.                               |
| · <b>Evaporation rate</b>                        | Not determined.                               |
| · <b>Solubility in / Miscibility with water:</b> | Fully miscible.                               |
| · <b>Partition coefficient: n-octanol/water:</b> | Not determined.                               |
| · <b>Viscosity:</b>                              |   |
| Dynamic:   | Not determined.                               |
| Kinematic:                                       | Not determined.                               |
| · <b>Solvent content:</b>                        |   |
| Organic solvents:                                | 4.0 %   |
| Water:   | 74.0 %  |
| Solids content:                                  | 5.0 %   |
| · <b>9.2 Other information</b>                   | No further relevant information available.    |

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**  
Harmful if swallowed.

· **LD/LC50 values relevant for classification:**

**ATE (Acute Toxicity Estimates)**

|            |          |                      |
|------------|----------|----------------------|
| Oral       | LD50     | 1,421 mg/kg          |
| Dermal     | LD50     | 8,489 mg/kg (rabbit) |
| Inhalative | LC50/4 h | 10.1 mg/l            |

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|  |          |                    |
|--|----------|--------------------|
| <b>3586-55-8 (Ethylendioxy)dimethanol</b>              |          |                    |
| Oral   | LD50     | 500 mg/kg (ATE)    |
| <b>111-30-8 glutaral</b>                               |          |                    |
| Oral   | LD50     | 100 mg/kg (ATE)    |
| Inhalative   | LC50/4 h | 0.5 mg/l (ATE)     |
| <b>5538-94-3 N,N-Dimethyl-N-Dioctylammoniumchlorid</b> |          |                    |
| Oral   | LD50     | 238 mg/kg (rat)    |
| Dermal   | LD50     | 191 mg/kg (rabbit) |

- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation**  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**  
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water  
Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
Must not reach sewage water or drainage ditch undiluted or unneutralised.  
Danger to drinking water if even extremely small quantities leak into the ground.  
Very toxic for aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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|                                   |  |
|-----------------------------------|--|
| · <b>European waste catalogue</b> |  |
| 07 00 00                          | WASTES FROM ORGANIC CHEMICAL PROCESSES   |
| 07 06 00                          | wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics |
| 07 06 99                          | wastes not otherwise specified   |

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

### SECTION 14: Transport information

|   |   |
|---|---|
| · <b>14.1 UN-Number</b><br>· <b>ADR, IMDG, IATA</b>   | UN1903  |
| · <b>14.2 UN proper shipping name</b><br>· <b>ADR</b><br><br>· <b>IMDG</b><br><br>· <b>IATA</b>           | 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (glutaral)<br>DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (glutaral), MARINE POLLUTANT<br>DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (glutaral) |
| · <b>14.3 Transport hazard class(es)</b><br>· <b>ADR, IMDG</b>  |                 |
| · <b>Class</b><br>· <b>Label</b>  | 8 Corrosive substances.<br>8  |
| · <b>IATA</b>   |    |
| · <b>Class</b><br>· <b>Label</b>  | 8 Corrosive substances.<br>8  |
| · <b>14.4 Packing group</b><br>· <b>ADR, IMDG, IATA</b>   | III   |
| · <b>14.5 Environmental hazards:</b><br>· <b>Marine pollutant:</b><br><br>· <b>Special marking (ADR):</b> | No<br>Symbol (fish and tree)<br>Symbol (fish and tree)  |
| · <b>14.6 Special precautions for user</b><br>· <b>Hazard identification number (Kemler code):</b>        | Warning: Corrosive substances.<br>80  |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>                          | Not applicable.   |
| · <b>Transport/Additional information:</b>  |   |
| · <b>ADR</b><br>· <b>Excepted quantities (EQ):</b>  | E1  |

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|                                   |  |
|-----------------------------------|--|
| · <b>Limited quantities (LQ)</b>  | 5L   |
| · <b>Excepted quantities (EQ)</b> | -  |
|                                   | Code: E1   |
|                                   | Maximum net quantity per inner packaging: 30 ml                    |
|                                   | Maximum net quantity per outer packaging: 1000 ml                  |
| · <b>Transport category</b>       | 3  |
| · <b>Tunnel restriction code</b>  | E  |
| · <b>IMDG</b>                     |  |
| · <b>Limited quantities (LQ)</b>  | 5L   |
| · <b>Excepted quantities (EQ)</b> | Code: E1   |
|                                   | Maximum net quantity per inner packaging: 30 ml                    |
|                                   | Maximum net quantity per outer packaging: 1000 ml                  |
| · <b>UN "Model Regulation":</b>   | UN 1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (GLUTARAL), 8, III |

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008 GHS label elements
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Cutoms tariff No.: 3808 9490

· **Relevant phrases**

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

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

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Abteilung Produktsicherheit

- **Contact:** Hr. Dr. Metz

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
 EINECS: European Inventory of Existing Commercial Chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 LC50: Lethal concentration, 50 percent  
 LD50: Lethal dose, 50 percent  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative  
 Acute Tox. 3: Acute toxicity - oral – Category 3  
 Acute Tox. 4: Acute toxicity - oral – Category 4  
 Acute Tox. 2: Acute toxicity - inhalation – Category 2  
 Skin Corr. 1B: Skin corrosion/irritation – Category 1B  
 Skin Irrit. 2: Skin corrosion/irritation – Category 2  
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
 Resp. Sens. 1: Respiratory sensitisation – Category 1  
 Skin Sens. 1: Skin sensitisation – Category 1  
 Skin Sens. 1A: Skin sensitisation – Category 1A  
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3  
 Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1  
 Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1  
 Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2  
 \* **Data compared to the previous version altered.**

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