

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 08.08.2023

Version number 6 (replaces version 5)

Revision: 08.08.2023

Start

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: Prisma Gloss**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Polishing paste
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dentsply DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:** Research and Development
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

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

· **Dangerous components:**

CAS: 1344-28-1 EINECS: 215-691-6	Aluminiumoxid	substance with a Community workplace exposure limit	50 – 100%
CAS: 56-81-5 EINECS: 200-289-5	glycerol	substance with a Community workplace exposure limit	25 – 50%

- **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** No special measures required.
- **After inhalation** Supply fresh air; consult doctor in case of complaints.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.

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- **After swallowing** If symptoms persist consult doctor.
- **Information for doctor** No further relevant information available.
- **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.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents** Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **Handling** Product is intended for dental use only.
- **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:** Store receptacle in a well ventilated area.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**

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

CAS: 1344-28-1 Aluminiumoxid

WEL Long-term value: 10* 4** mg/m³
*inhalable dust **respirable dust

CAS: 56-81-5 glycerol

WEL Long-term value: 10 mg/m³

- **Regulatory information** WEL: EH40/2020
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.

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- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
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.
Nitrile rubber, NBR
Permeation: Level ≥ 6
Recommended thickness of the material: ≥ 0.11 mm
- **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.
- **Eye/face protection** Safety glasses
- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid.
- **Colour:** Opaque
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** undetermined
- **Boiling point or initial boiling point and boiling range** 290 °C (Glycerol)
- **Flammability** Not determined.
- **Lower and upper explosion limit**
- **Lower:** 2.6 Vol %
- **Upper:** 11.3 Vol %
- **Flash point:** 199 °C (Glycerol)
- **Auto-ignition temperature:** 400 °C (Glycerol)
- **Decomposition temperature:** Not determined.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **dynamic:** Not applicable.
- **Solubility**
- **Water:** Insoluble
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not applicable.
- **Density and/or relative density**
- **Density at 20 °C:** 1.7 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not applicable.

9.2 Other information

- **Appearance:**
- **Form:** Pasty

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- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Solvent content:**
- **Organic solvents:** 48.0 %
- **Solids content:** 50.0 %
- **Change in condition**
- **Evaporation rate** Not applicable.
- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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

CAS: 1344-28-1 Aluminiumoxid

Oral	LD50	> 5,000 mg/kg (rat)
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CAS: 56-81-5 glycerol

Oral	LD50	12,600 mg/kg (rat)
Dermal	LD50	> 18,700 mg/kg (rabbit)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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- **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** Based on available data, the classification criteria are not met.
- **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.
- **11.2 Information on other hazards**

· Endocrine disrupting properties
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None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 56-81-5 glycerol

LC50/24h	> 5,000 mg/l (Fish acute toxicity study)
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EC50/24h	> 10,000 mg/L (daphnia magna)
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- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- | | |
|--|-----------------|
| · 14.1 UN number or ID number | |
| · ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · 14.4 Packing group | |
| · ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |

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· 14.6 Special precautions for user	Not applicable.
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· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
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· UN "Model Regulation":	Void
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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

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

- *** Data compared to the previous version altered.**

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