

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

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

1.1 Product identifier

Product name: PoloDent® Zircon Prophy Paste
Article number: 73 80 80

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

Use of substance/mixture: No further relevant information available.
Polishing agent/ Burnishing compound

1.3 Details of the supplier of the safety data sheet

Manufacturer: PRISMAN GmbH
Otto Hahn Ring 6-18
D-64653 Lorsch
Germany

Distributor: Polo MB Oisterwijk BV
Laarakkerweg 5
5061 JR Oisterwijk
The Netherlands
www.polodent.com

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: The product is not classified, according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]: Void
Hazard pictograms: Void
Signal word: Void
Hazard statements: Void

2.3 Other hazards

Results of PBT and vPvB assessment Not applicable

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 56-81-5 EINECS: 200-289-5 RTECS: MA 8050000	glycerol substance with a Community workplace exposure limit	25-50%
--	---	--------

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

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

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:	Generally the product does not irritate the skin.
After eye contact:	Rinse opened eye for several minutes under running water.
After swallowing:	If symptoms persist consult doctor.
Inhalation:	In case of unconsciousness place patient stably in side position for transportation.

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.
---------------------------------------	--

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

Not required

6.2 Environmental precautions

Environmental precautions:	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).

6.4 Reference to other sections

Reference to other sections:	No dangerous substances are released.
-------------------------------------	---------------------------------------

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Information about fire -
and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by
storerooms and receptacles: No special requirements.

Information about storage in one
common storage facility: Not required.

Further information about
storage conditions: None.

7.3 Specific end use(s)

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:

56-81-5 glycerol	
WEL	Long-term value: 10 mg/m ³

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

8.1 Control parameters

General protective and
hygienic measures: The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not required.

Hand protection: Not required.

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
For the permanent contact of a
maximum of 15 minutes gloves
made of the following materials
are suitable: The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Natural rubber, NR
Butyl rubber, BR

Eye protection: Not required.

MEDICAL DEVICE**SAFETY DATA SHEET**

POLO MB OISTERWIJK BV

Product name: PoloDent Zircon Prophy Paste

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form:	Pasty
Colour:	Cream colored
Odour:	Pleasant
pH-value:	Not applicable
Change in condition:	
- Melting point/freezing point:	Undetermined.
- Initial boiling point and boiling range:	100 °C
Flash point:	160 °C
Ignition temperature:	370 °C
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
- Lower	Not applicable.
- Upper	Not applicable.
Vapour pressure at 20 °C:	23 hPa
Density at 20 °C:	1.3 g/cm ³
Solubility in / Miscibility with water:	Partly miscible.
Solvent content:	
VOC (EC)	0 %
Solids content:	> 50 %

9.2 Other information

Other information:	No further relevant information available
---------------------------	---

SECTION 10: Stability and reactivity

10.1 Reactivity

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

Hazardous reactions:	No dangerous reactions known.
-----------------------------	-------------------------------

10.4 Conditions to avoid

Conditions to avoid:	No further relevant information available.
-----------------------------	--

10.5 Incompatible materials

Materials to avoid:	No further relevant information available.
----------------------------	--

10.6 Hazardous decomposition products

Haz. decomp. products:	No dangerous decomposition products known.
-------------------------------	--

SECTION 11: Toxicological information

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

11.1 Information on toxicological effects

Acute toxicity: Based on available data, the classification criteria are not met.

ATE (Acute Toxicity Estimates)

Oral	LD50	26,000 mg/kg (rat)
------	------	--------------------

Oral	LD50	12,600 mg/kg (rat)
------	------	--------------------

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.
CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction): Based on available data, the classification criteria are not met.
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: 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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability

Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential

Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil

Mobility: No further relevant information available.

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.5 Results of PBT and vPvB assessment

PBT identification: Not applicable.

vPvB identification: Not applicable.

12.6 Other adverse effects

Other adverse effects: No further relevant information available.

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation: Smaller quantities can be disposed of with household waste.

European waste catalogue:

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 07	chemicals other than those mentioned in 18 01 06

Uncleaned packaging: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number

ADR, ADN, IMDG, IATA: Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG:

- Class: Void

IATA:

- Class: Void

- Label: -

14.4 Packing group

ADR, IMDG, IATA: Void

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

Danger code (Kemler): -

EMS Number: -

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

Transport/Additional information: Not dangerous according to the above specifications.

ADR:

- Excepted quantities (EQ): -

- Limited quantities (LQ): -

- Transport category: Kein Gefahrgut

UN "Model Regulation": UN-, -

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Zircon Prophy Paste

POLO MB OISTERWIJK BV

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

15.2 Chemical safety assessment

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

SECTION 16: Other information

16.1 Other information

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.

Recommended restriction of use: Product only for professional use

Abbreviations and acronyms: RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
 ICAO: International Civil Aviation Organisation
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
 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
 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)
 VOC: Volatile Organic Compounds (USA, EU)
 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.**