

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent Prophylaxis Powder Classic

POLO MB OISTERWIJK BV

SECTION 1:

Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: PoloDent® Prophylaxis Powder Classic
Article number(s): 52 02 00 Mint
 52 02 05 Lemon
 52 02 10 Cherry
 52 02 15 Cassis

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

Use of substance/mixture: No further relevant information available.
 Polishing powder

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 [CLP]: The substance 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

PBT/vPvB: This product is not identified as a PBT/vPvB substance.

SECTION 3:

Composition/information on ingredients

3.1 Chemical characterisation

Description: Substances

CAS: 144-55-8
 EINECS: 205-633-8

Sodium hydrogencarbonate

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SECTION 4: First aid measures

4.1 Description of first aid measures

General information:	No special measures required.
Inhalation:	Supply fresh air; consult doctor in case of complaints.
Skin contact:	Generally the product does not irritate the skin.
Eye contact:	Rinse opened eye for several minutes under running water.
Swallowing:	If symptoms persist consult doctor.

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:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
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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.
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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.
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6.3 Methods and material for containment and cleaning up

Pick up mechanically.

6.4 Reference to other sections

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.
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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Precautions for safe handling No special measures required.

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: 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. Store in upright position.

7.3 Specific end use(s)

Specific end use(s): No further relevant information available.

SECTION 8: Exposure controls / personal protection

Additional information about design of technical facilities

No further data; see item 7.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

Not required.

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

8.2 Exposure controls

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection:

Suitable respiratory protective device recommended.

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.

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 of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

Nitrile rubber, NBR

Natural rubber, NR

Eye protection:

Safety glasses.

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SECTION 9:
Physical and chemical properties
9.1 Information on basic physical and chemical properties

Form:	Like powder.
Colour:	White
Odour:	Recognisable
Odour threshold:	Not determined.
pH (at 20°C):	8,1-8,4
Flash point (°C):	Not applicable.
Flammability (solid, gas):	Product is not flammable.
Ignition temperature:	
- Decomposition temperature	Not determined.
Auto-ignition temperature:	Not determined.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
- Lower	Not determined.
- Upper	Not determined.
Vapour pressure (at 20°C):	Not applicable.
Density (at 20°C):	Not determined.
Bulk density at 20 °C:	1100 kg/m ³
- Relative density	Not determined.
- Vapour density	Not applicable.
- Evaporation rate	Not applicable.
Solubility in / Miscibility with water (at 20°C):	95 g/l
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
- Dynamic	Not applicable.
- Kinematic	Not applicable.
- Organic solvents	0,0%
Solids content:	100%

9.2 Other information

Other information:	No further relevant information available.
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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

11.1 Information on toxicological effects

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

SODIUM HYDROGENCARBONATE

Oral	RAT	LD50	4220 mg/kg
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Primary irritant effect:

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.

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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) (assessment by list): 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: This product is not identified as a PBT/vPvB substance.

12.6 Other adverse effects

Other adverse effects: No further relevant information available.

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 02 00	wastes from research, diagnosis, treatment or prevention of disease involving animals
18 02 06	chemicals other than those mentioned in 18 02 05

Uncleaned packaging: Recommendation: Dispose of packaging according to regulations on the disposal of packagings.

Recommended cleansing agents: Water, if necessary together with cleansing agents.

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SECTION 14: Transport information

14.1 UN number

ADR, IMDG, IATA: Void

14.2 UN proper shipping name

ADR, IMDG, IATA: Void

14.3 Transport hazard class(es)

ADR, IMDG, IATA: Void

14.4 Packing group

ADR, IMDG, IATA: Void

14.5 Environmental hazards

Hazards: Not applicable.

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

Not applicable.

Transport/Additional information:

ADR:

- Limited quantities (LQ):

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- Transport category:

-

UN "Model Regulation":

Void

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

Substance is not listed.

15.2 Chemical safety assessment

Chemical safety assessment:

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

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**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.

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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial 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

Legal disclaimer:

The information supplied in this Safety Data Sheet is designed only as guidance for the safe use, storage and handling of the product. This information is correct to the best of our knowledge and belief at the date of publication however no guarantee is made to its accuracy, reliability or completeness. This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any other process. It is the user's responsibility to satisfy him/herself as to the suitability of such information for his /her own particular use.