

MEDICAL DEVICE

SAFETY DATA SHEET

Product name:
PoloDent APC Universal

POLO MB OISTERWIJK BV

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

1.1 Product identifier

Product name:	PoloDent® APC Universal			
Article number:	Syringe:		Capules:	
	38 22 30	A1	38 22 95	A1
	38 22 35	A2	38 23 00	A2
	38 22 40	A3	38 23 05	A3
	38 22 45	A3.5	38 23 10	A3.5
	38 22 50	A4	38 23 15	A4
	38 22 55	B1	38 23 20	B1
	38 22 60	B2	38 23 25	B2
	38 22 65	B3	38 23 30	B3
	38 22 70	C2	38 23 35	C2
	38 22 80	BW	38 23 45	BW

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

Use of substance/mixture: Dental product

1.3 Details of the supplier of the safety data sheet

Manufacturer: DS Dental Supply GmbH
22607 Hamburg, Germany
info@ds-dental-supply productions

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

1.4 Emergency telephone number

++49 (0)4121 483-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008: Skin Irrit. 2, H315 Causes skin irritation
Eye Irrit. 2, H319 Causes serious eye irritation
Skin Sens. 1; H317 May cause allergic skin reaction

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

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SECTION 2 (continued): Hazards identification

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]:

Hazard pictograms:



Signal word:

Warning

Hazard statements:

H315 - Causes skin irritation
H319 - Causes serious eye irritation
H317 - May cause allergic skin reaction

Precautionary statements:

P280 - Wear protective gloves/protective clothing/eye protection/face 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.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

PBT: not applicable
vPvB: not applicable

SECTION 3: Composition/information on ingredients

3.2 Chemical characterization

Description: Mixture of poly- and difunctional methacrylates, barium glass filler, fumed silica, photoinitiator, accelerator, stabilizer.

Hazardous components:

Methacrylates GHS07, H315, H319, H317, H335

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product.
After skin contact: Wash with plenty of water and soap.
After inhalation: Fresh air.
After eye contact: Rinse with plenty of water and consult a doctor.
After swallowing: If symptoms persist consult a doctor.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, powder, water spray.
Use extinguishing method and media suitable to surrounding fire.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: Wear self-contained respiratory protective equipment.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Not required

6.2 Environmental precautions

Do not allow to enter drains/surface water/ ground-water.

6.3 Methods for cleaning up

Pick up mechanically. Clean up affected area.

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 Handling

Handling: This product should only be supplied or handled to dentists or dental technicians or upon their instructions.
Information for safe handling: Observe normal care for working with chemicals.
Information about fire and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store at a dry place. Store tightly closed. Storage temperature <25°C.

Requirements at storerooms and containers: Store only in the original containers.

Further information on storage conditions: Store away from food stuffs.

7.3 Specific end use(s)

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

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SECTION 8: Exposure controls / personal protection

8.1 Components with limits of values to be supervised at the workplace

The product contains no relevant quantities of components with limits of values to be supervised at the workplace.

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

8.2 Personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals. Keep away from foodstuffs and beverages. Avoid contact with eyes or skin.

Hand protection:

Protective gloves.
Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection:

Safety glasses

Respiratory protection:

Required, when aerosols are generated

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Form: Paste
Colour: Tooth colored
Odour: Odorless

Safety relevant basic data

Melting point/melting range: n.a.
Boiling point/boiling range: n.a.
Flash point: n.d.
Ignition temperature: n.d.
Danger of explosion: none
Density: 1.90 (20°C) g/cm³
Vapor pressure: n.a.
pH: neutral
Solubility in/miscibility with: Partially soluble in toluene, silicone oil
Water: insoluble
Content of solvents: none
Organic solvents: none

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SECTION 10: Stability and reactivity

10.1 Thermal decomposition / conditions to be avoided

Possibility of hazardous reactions: No information available.
Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.

10.2 Hazardous decomposition products

Hazardous decomposition products: No information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: No data available.

Primary irritation:

skin: irritant
eye: irritant
Sensitization: sensitization by skin contact possible

11.2 Additional toxicological information

Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

SECTION 12: Ecological information

General information: Avoid transfer into environment.

Classification of water endangerment: WGK=1 (slightly polluting substance).

SECTION 13: Disposal considerations

13.1 Product

Recommendation: Small quantities can be disposed of with household waste.
Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

13.2 Uncleaned packaging

Recommendation: Disposal must be made according to official regulations.

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SECTION 14: Transport information

Land transport ADR/RID and GGVS/GGVE (Germany):

no subject to transport regulations.

Sea transport IMDG:

no subject to transport regulations.

Air transport ICAO-TI and IATA-DGR:

no subject to transport regulations.

SECTION 15: Regulatory information

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Changes compared with the previous version:

Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.