MEDICAL DEVICE
SAFETY DATA SHEET

POLO MB OISTERWIJK BV

Product name:
PoloDent APC Universal

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

1.1 Product identifier

Product name: PoloDent® APC Universal

Article number:

382230	PoloDent APC Universal syringe A1 4 g
382235	PoloDent APC Universal syringe A2 4 g
382240	PoloDent APC Universal syringe A3 4 g
382245	PoloDent APC Universal syringe A3,5 4 g
382250	PoloDent APC Universal syringe A4 4 g
382255	PoloDent APC Universal syringe B1 4 g
382260	PoloDent APC Universal syringe B2 4 g
382265	PoloDent APC Universal syringe B3 4 g
382270	PoloDent APC Universal syringe C2 4 g
382275	PoloDent APC Universal syringe OA2 4 g
382295	PoloDent APC Universal capsules A1 20x 0,2 g
382300	PoloDent APC Universal capsules A2 20x 0,2 g
382305	PoloDent APC Universal capsules A3 20x 0,2 g
382310	PoloDent APC Universal capsules A3,5 20x 0,2 g
382315	PoloDent APC Universal capsules A4 20x 0,2 g
382320	PoloDent APC Universal capsules B1 20x 0,2 g
382325	PoloDent APC Universal capsules B2 20x 0,2 g
382330	PoloDent APC Universal capsules B3 20x 0,2 g
382335	PoloDent APC Universal capsules C2 20x 0,2 g
382340	PoloDent APC Universal capsules OA2 20x 0,2 g

Product type: Paste.

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

Product use: Dental product: Composite

Area of application: Professional applications.

1.3 Details of the supplier of the safety data sheet

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

SECTION 2:
Hazards identification

2.1 Classification of the substance or mixture

OSHA/HCS status: This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Health effects are based on the uncured material.

Classification of the substance or mixture:
SKIN IRRITATION - Category 2
EYE IRRITATION - Category 2A
Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 93.2%

2.2 Label elements

Hazard pictograms:

GHS02

Signal word (CLP): Warning

Hazard statements:
Causes serious eye irritation.
Causes skin irritation.

Precautionary statements
Prevention: Wear protective gloves. Wear eye or face protection. Wash hands thoroughly after handling.

Response: IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Storage: Not applicable.
Disposal: Not applicable.
Hazards not otherwise classified: None known.

SECTION 3: Composition/information on ingredients

3.2 Substance/mixture

Substance/mixture: Mixture
Other means of identification: Not available.

CAS number/other identifiers
CAS number: Not applicable.
Product code: Not available.

INGREDIENT NAME	OTHER NAMES	%	CAS NUMBER
7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXA-DECANE-1,16-DIYL BISMETHACRYLATE	Urethane dimethacrylate	5 - 10	72869-86-4
1,6-HEXANEDIYL BISMETHACRYLATE	1,6-hexanediyl bismethacrylate	5 - 10	6606-59-3

Any concentration shown as a range is to protect confidentiality or is due to batch variation.
There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact: No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.

Inhalation: No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.

Skin contact: No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects
Eye contact: Causes serious eye irritation.

Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact: Causes skin irritation.

Ingestion: No known significant effects or critical hazards.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact: Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation: No specific data.

Skin contact: Adverse symptoms may include the following:
irritation
redness

Ingestion: No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments: No specific treatment.

Protection of first-aiders: In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media: Do not use water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards arising from the chemical: No specific fire or explosion hazard.

Hazardous thermal decomposition products: Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
metal oxide/oxides

5.3 Advice for fire-fighters

Special protective actions for fire-fighters: In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Low release. For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely

For emergency responders: Low release. See also the information in “For non-emergency personnel”.

Environmental precautions: Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.2 Environmental precautions

Environmental precautions: Low release. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container.

Large spill: Small Quantity. For professional use only. Absorb with an inert material and place in an appropriate waste disposal container..

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures: No special measures are required for small quantities under normal and intended conditions of product use. For professional use only. Put on appropriate personal protective equipment (see Section 8). Handle with care and dispose in a safe manner.

Advice on general occupational hygiene: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Conditions for safe storage, including any incompatibilities: Store between the following temperatures: 20 to 25°C (68 to 77°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits: None.

Appropriate engineering controls: No special measures are required for small quantities under normal and intended conditions of product use.

Environmental exposure controls: No special measures are required for small quantities under normal and intended conditions of product use.

8.2 Individual protection measures

Hygiene measures: No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

8.3 Skin protection

Hand protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection: No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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Product name:
PoloDent APC Universal

SECTION 9:
Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance **Physical state:**	Solid. [Paste.]
Color:	Various
Odor:	Fruity ester-like
Odor threshold:	Not available.
pH :	Not available.
Melting point :	Not available.
Boiling point :	Not available.
Flash point :	Not available.
Evaporation rate:	Not available.
Flammability (solid, gas):	Not available.
Lower and upper explosive: (flammable) limits	Not available.
Vapor pressure:	Not available.
Vapor density:	Not available.
Relative density:	1.8 to 1.9
Solubility:	Not available.
Solubility in water:	Not available.
Partition coefficient: noctanol/ water:	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
SADT:	Not available.
Viscosity:	Not available.

SECTION 10:
Stability and reactivity

10.1 Reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability

Chemical stability: The product is stable.

10.3 Possibility of hazardous reactions

Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.

10.4 Conditions to avoid

Conditions to avoid: Keep away from heat and direct sunlight. Initiators.

10.5 Incompatible materials

Incompatible materials: Reactive or incompatible with the following materials: oxidizing materials and reducing materials.
Peroxide.

10.6 Hazardous decomposition products

Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Not available.

Conclusion/Summary: Based on analysis and test results, this product is considered as biocompatible per EN ISO 7405:2008 and EN ISO 10993-1:2009.

Irritation/Corrosion: Not available.

Sensitization: Not available.

Conclusion/Summary Skin: Kligman score: Grade I (weak sensitizer)

Mutagenicity: Not available.

Conclusion/Summary: No mutagenic effect.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Teratogenicity: Not available.

Specific target organ toxicity (single exposure)

NAME	CATEGORY	ROUTE OF EXPOSURE	TARGET ORGANS
7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADE-CANE-1,16-DIYL BISMETHACRYLATE	Category 3	Not applicable.	Respiratory tract irritation
1,6-HEXANEDIYL BISMETHACRYLATE	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure): Not available.

Aspiration hazard: Not available.

Information on the likely routes of exposure: Routes of entry anticipated: Oral, Dermal, Inhalation.

11.2 Potential acute health effects

Eye contact: Causes serious eye irritation.

Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact: Causes skin irritation.

Ingestion: No known significant effects or critical hazards.

11.3 Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation: No specific data.

Skin contact: Adverse symptoms may include the following:
irritation
redness

Ingestion: No specific data.

11.4 Delayed and immediate effects and also chronic effects from short and long term exposure Short term exposure

Potential immediate effects: Not available.

Potential delayed effects: Not available.

11.5 Long term exposure

Potential immediate effects: Not available.

Potential delayed effects: Not available.

11.6 Potential chronic health effects

Potential chronic health effects: Not available.

General: No known significant effects or critical hazards.

Carcinogenicity: No known significant effects or critical hazards.

Mutagenicity: No known significant effects or critical hazards.

Mutagenicity: No known significant effects or critical hazards.

Developmental effects: No known significant effects or critical hazards.

Fertility effects: No known significant effects or critical hazards.

11.7 Numerical measures of toxicity

Acute toxicity estimates

ROUTE	ATE VALUE
ORAL	4310 mg/kg

SECTION 12: Ecological information

12.1 Toxicity

Toxicity: Not available.

Persistence and degradability: Not available.

12.2 Bioaccumulative potential

PRODUCT/INGREDIENT NAME	$LogP_{ow}$	BCF	POTENTIAL
7,7,9(OR 7,9,9)-TRIMETHYL-4, 13-DIOXO-3,14-DIOXA-5, 12-DIAZAHEXADECANE-1, 16-DIYL BISMETHACRYLATE	3	-	low

12.3 Mobility in soil

Soil/water partition coefficient (KOC): Not available.

Other adverse effects: No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Disposal methods

Disposal methods: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

SECTION 14: Transport information

14.1 UN number

	DOT CLASSIFICATION	IMDG	IATA
UN NUMBER	Not regulated.	Not regulated.	Not regulated.
UN PROPER SHIPPING NAME	-	-	-
TRANSPORT HAZARD CLASS(ES)	-	-	-
PACKING GROUP	-	-	-
ENVIRONMENTAL HAZARDS	No.	No.	No.
ADDITIONAL INFORMATION	-	-	-

Special precautions for user: **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not available.

section 15: Regulatory information

15.1 Regulatory information

U.S. Federal regulations: **TSCA 8(a) PAIR:** mequinol
United States inventory (TSCA 8b): All components are listed or exempted

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs): Not listed

Clean Air Act Section 602 Class I Substances: Not listed

Clean Air Act Section 602 Class II Substances: Not listed

DEA List I Chemicals (Precursor Chemicals): Not listed

DEA List II Chemicals (Essential Chemicals) Not listed

15.2 SARA 302/304

Composition/information on ingredients

NAME	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(LBS)	(GALLONS)	(LBS)	(GALLONS)
1,4-DIHYDROXYBENZENE	0 - 0.1	Yes.	500 / 10000	-	100	-

SARA 304 RQ: 163398.7 lbs / 74183 kg

15.3 SARA 311/312

Classification: Immediate (acute) health hazard

Composition/information on ingredients

NAME	%	FIRE HAZARD	SUDDEN RELEASE OF PRESSURE	REACTIVE	IMMEDIATE (ACUTE) HEALTH HAZARD	DELAYED (CHRONIC) HEALTH HAZARD
7,7,9(OR 7,9,9)-TRIMETHYL-4,13-DIOXO-3,14-DIOXA-5,12-DIAZAHEXADECANE-1,16-DIYL BISMETHACRYLATE	5 - 10	No.	No.	Yes.	Yes.	No.
1,6-HEXANEDIYL BISMETHACRYLATE	5 - 10	No.	No.	Yes.	Yes.	No.

15.4 SARA 313

SARA 313: Not applicable.

SECTION 16: Other information

16.1 Other information

Key to abbreviations:

ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. (“Marpol” = marine pollution)
UN = United Nations

Legal disclaimer:

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.