

**Safety Information Sheet for Medical Devices  
following 1907/2006/EG, Article 31**

Date of issue: 12.08.2024  
Printing date: 12.08.2024

Version: 1.1

This product is a medical device as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/745 (MDR), which is invasive or used in direct physical contact with the human body. For this product a safety data sheet is not legally required. The provision of this document is on a voluntary basis.

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

**1.1 Product identifier**

**Trade name:**

**Enigma PMMA Primer**

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

**Identified uses:**

Dental product.

**Restrictions on use:**

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

**1.3 Details of the supplier of the safety information sheet**

**Manufacturer/supplier:**

SanaPro Dental GmbH  
Stresemannstrasse 46  
27570 Bremerhaven, Germany  
dentalproducts@sanapro.dental

**Distributor:**

Davis Schottlander & Davis Ltd.  
Fifth Avenue, Letchworth Garden City  
GB-SG6 2WD Herts, United Kingdom  
Phone: 0044 146 248 0848

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

Medical devices as defined in Directive 93/42/EEC on medical devices (MDD) respectively Regulation (EU) 2017/245, which are invasive or used in direct physical contact with the human body are exempt from labeling requirements of Regulation (EC) No. 1272/2008 (CLP/GHS). Although not required, classification and labeling are indicated as follows:

**Classification:**

Flammable liquid, Category 2, H225 Highly flammable liquid and vapour

Skin irritation, Category 2; H315 Causes skin irritation.

Skin sensitization, Category 1; H317 May cause allergic skin reaction.

Specific target organ toxicity – single exposure (STOT SE), Category 3; H335 May cause respiratory irritation.

**2.2 Label elements**

**CLP Regulation (EC) No. 1272/2008**

**Signal word:**

Danger.

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**Hazard pictograms:**



GHS02



GHS07

**Hazard statements:**

H225 Highly flammable liquid and vapour

H315 Causes skin irritation.

H317 May cause allergic skin reaction.

H335 May cause respiratory irritation.

**Precautionary statements:**

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

**2.3 Other hazards**

**Results of PBT and vPvB assessment:**

PBT: not applicable.

vPvB: not applicable.

**SECTION 3: Composition/information on ingredients**

**3.1 Substances**

Not applicable.

**3.2 Mixtures**

**Chemical characterization (description):**

Difunctional methacrylates, methyl methacrylate and photoinitiators.

**Hazardous components:**

CAS-No. 80-62-6 Methyl methacrylate GHS02, GHS07, H225, H315, 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.

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**SECTION 5: Firefighting measures**

**5.1 Extinguishing media**

**Extinguishing media:**

CO<sub>2</sub>, extinguishing 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.

**Protective equipment:**

Wear self-contained respiratory protective equipment.

**SECTION 6: Accidental release measures**

**6.1 Personal precautions, protective equipment and emergency procedures**

**Personal precautions:**

Do not inhale vapours/aerosols. Avoid substance contact. Ensure supply of fresh air in enclosed rooms.

**6.2 Environmental precautions**

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

**6.3 Methods and material for containment and cleaning up**

Absorb with liquid binding material. Clean up affected area. Ensure fresh air.

**6.4 Reference to other sections**

See Section 7: Handling and storage

See Section 8: Exposure controls/personal protection

See Section 13: Disposal considerations

**SECTION 7: Handling and storage**

**7.1 Precautions for safe 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:**

Keep away from sources of ignition.

**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.

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**Information about storage in one common storage facility:**

Store away from food stuffs.

**Further information on storage conditions:**

None.

**Storage class:**

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**7.3 Specific end use(s)**

No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

**8.1 Control parameters**

**Additional information on the design of technical systems:**

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**Components with limits of values to be supervised at the workplace:**

CAS-No.	name	art	value	unit
80-62-6	Methyl methacrylate	TRGS 900	210	mg/m <sup>3</sup>
		Or	50	ml/m <sup>3</sup>

**Additional information:**

The lists valid during the making were used as basis.

**8.2 Exposure controls**

**Personal protective equipment:**

**General protective and hygienic measures:**

Normal 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.

**Respiratory protection:**

Required, when aerosols are generated.

**Hand protection:**

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

**Eye protection:**

Safety glasses.

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Appearance:**

Form:	liquid
Color:	colorless
Odor:	characteristic

**Change in condition:**

Melting point/melting range: not applicable

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Boiling point/boiling range:	100 °C	
Flash point:	10 °C DIN 51794	
Ignition temperature:	no information available	
Danger of explosion:	lower limit of explosion:	2.1 Vol %
	upper limit of explosion:	12.5 Vol %
Density:	~ 1.0 (20°C) g/cm <sup>3</sup>	
Vapor pressure:	not determined	
Solubility in/miscibility with:		
Water:	slightly soluble	
Content of solvents:	none	
Organic solvents:	none	

#### **SECTION 10: Stability and reactivity**

##### **10.1 Reactivity**

Expected to be non-reactive under normal conditions of use.

##### **10.2 Chemical stability**

The product is stable by proper use and storage.

##### **10.4 Conditions to avoid**

Heat, sunlight, peroxides, radical initiators.

##### **10.6 Hazardous decomposition products**

No information available.

#### **SECTION 11: Toxicological information**

##### **11.1 Information on toxicological effects**

###### **Acute toxicity:**

LD50 (oral, rat)            7872 mg/kg.

###### **Primary irritation:**

**Skin:**                        irritant.

**Eye:**                         irritant.

**Sensitization:**            sensitization by skin contact possible.

###### **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 hazardous to water:**

Water hazard class 1 (self-classification): slightly hazardous to water.

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**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

**Recommendation:**

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

**Uncleaned packaging:**

**Recommendation:**

Disposal must be made according to official regulations.

**SECTION 14: Transport information**

**Land transport ADR/RID and GGVSE (Germany):**

UN 1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT, GEMISCH, 3,II.

**Sea transport IMDG Code:**

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, MIXTURE, 3, II

EmS: F-E S-D.

**Air transport ICAO-TI and IATA-DGR:**

UN 1247 METHYL METHACRYLATE, MONOMER, STABILIZED, MIXTURE, 3, II..

The transport regulations are cited according to international regulations and in the form applicable in Germany. Possible national deviations in other countries are not considered.

**SECTION 15: Regulatory information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

**National regulations:**

Water hazard class 1 (self-classification): slightly hazardous to water.

**15.2 Chemical safety assessment**

A chemical safety assessment has not been carried out.

**SECTION 16: Other information**

For invasive medical devices or medical devices in direct contact with the human body, the Medical Device Regulation does not require a safety data sheet. The safe use of the product is indicated in the instructions for use and/or the labeling.

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. Users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.