

1. IDENTIFICATION OF SUBSTANCES / PREPARATION AND COMPANY

Product Name: Enigma PMMA Primer
 Product Code: 0386

Application: Dentistry

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2. HAZARD IDENTIFICATION

Classification of the substance or mixture

This substance is classified as hazardous according to GHS.

Regulation EC1272/2008

Physical	H225	Flammable Liquids	Hazard category 2
Health	H315	Irritation of skin	Hazard category 2
	H317	Skin sensitisation	Hazard category 1
	H335	Specific Target Organ Toxicity - Single exposure (inhalation)	Hazard category SE 3

Label elements

In Accordance with Regulation EC 1272/2008

Signal word Danger

GHS Pictogram



H315 H317 H335



H225

Hazard Statement	H225	Highly flammable liquid or vapour
	H315	Causes skin irritation
	H317	May cause an 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.

Labelling 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.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

In accordance with Regulation EC 1272/2008

Component	CAS No. EC Index No. REACH No. EINECS No.	Content	Hazard/category/statement
Methyl Methacrylate	80-62-6 607-035-00-6 01-2119452498-28 201-29701	>98%	Flam. Liq./2/H225 Skin Irrit./2/H315 Skin Sens./1/H317 STOT SE (inhalation)/3/H335

4. FIRST AID MEASURES**Description of first aid measures**

General advice	Medical treatment is necessary if symptoms occur which are obviously caused by skin or eye contact with the product, or by vapour inhalation. Remove soiled soaked clothing immediately.
Inhalation	Move casualty to fresh air and keep them calm. Seek medical attention.
Skin contact	Wash off immediately with soap and water. If skin irritation occurs, seek medical attention.
Eye contact	Holding eyelids open, immediately rinse thoroughly with plenty of water. Seek medical advice.
Ingestion	Rinse mouth immediately and drink plenty of water. Seek medical advice.

5. FIRE FIGHTING MEASURES**Extinguishing media**

Suitable extinguishing media: Foam, dry powder, carbon dioxide

Unsuitable extinguishing media: Water

Special hazards arising from the substance or mixture: No**Advice for fire fighters:** Wear self-contained breathing apparatus and full protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures
 Ensure adequate ventilation. Use personal protective clothing. Keep away from sources of ignition. Use breathing apparatus if exposed to vapour/dust/mist/aerosol.

Environmental procedures
 Do not allow to enter drains/surface water/ground water/sewerage systems. If entry occurs IMMEDIATELY alert The Environment Agency or other equivalent appropriate body.

Methods for cleaning up
 Absorb with liquid material. Forward for disposal. Clean up affected area.

Reference to other sections
 For safe handling see Section 7.
 For personal protection see section 8.
 For disposal considerations see section 13.

7. HANDLING AND STORAGE

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

Precautions for safe handling:
 Observe normal care for working with chemicals Information about fire and explosion protection: Keep away from sources of ignition. Take measure to prevent electrostatic charge.

Storage:
 Store at a dry place, protected from light. 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.

Specific end uses:
 No further relevant information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters:
 Components or products of decomposition according to point 10, with limit values related to the place of work which require monitoring.

Methyl Methacrylate	CAS No. 80-62-6	
WEL (8hrs)	208mg/m ³	50 ppm
WEL (15mins)	416 mg/m ³	100 ppm

Exposure controls:
 Derived No-Effect Level (DNEL)

Critical Component	Routes of Exposure (LONG-TERM)	DNEL
Methyl Methacrylate	Inhalation	210mg/m ³
	Dermal	74.3mg/m ³
	Oral	-

Predicted No-Effect Concentration (PNEC)

Critical Component	Routes of Exposure (LONG-TERM)	PNEC
Methyl Methacrylate	Water Soil Air	0.94mg/l - -

General protective measures: Do not inhale vapours. Avoid contact with eyes and skin.

Personal Protective Equipment:



Hygiene measures: Store work clothes separately. Remove soiled or soaked clothing immediately. Follow the usual good standards of occupational hygiene. Clean skin thoroughly after handling. Apply skin cream.

Respiratory protection: If ventilation is insufficient or aerosols or vapours are generated, breathing apparatus to be used in case of high concentrations, short term: filter appliance, filter A.

Hand protection: Butyl rubber gloves (0.7mm), break through time 60 minutes (EN 374:2004). In practice, due to variable exposure conditions, this information can only be used as an aid to selection of a suitable chemical protection glove. This information does not substitute suitability tests by the end user. A suitable glove type should be selected for each work environment. Gloves should be replaced regularly, especially after extended contact with the substance.

Eye protection: Wear approved, tightly fitting safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Form:	Liquid
Colour:	Colourless
Odour:	Characteristic
Melting Temperature:	n/a
Boiling Temperature:	100°C
Flashpoint:	10°C (method DIN 51755 - closed cup)
Ignition Temperature:	430°C (method DIN 51794)
Lower Explosion Limit:	2.1% vol. @ 10.5°C
Upper Explosion Limit:	12.5% vol.
Vapour Pressure:	n/a
Relative Density:	0.94g/cm ³ @ 20°C
Relative Vapour Density:	Ca.1g/cm ³
Solubility in Water:	1.6g/l @ 20°C, difficult to mix, slightly soluble
Solubility (Qualitative):	Miscible with most organic solvents
pH value:	Not applicable

Other information:

None

10. STABILITY AND REACTIVITY

Thermal decomposition / conditions to be avoided:

Possibility of hazardous reactions:

No information available

Conditions to avoid:

Warming > 50°C. Exposure to light. Polymerization possible in presence of heat, light, radical starters as peroxides, reducing agents, etc. Do not use various plastics or rubber as working materials.

Hazardous decomposition products:

No information available.

11. TOXICOLOGY INFORMATION

Acute toxicity: (methyl methacrylate)

LD50 (oral, rat) 7872 mg/kg

Primary irritation:

Skin: Irritant

Eye: Irritant

Sensitization: Sensitizing in case of skin contact possible

Additional toxicological information:

Allergic reactions to methacrylates 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.

12. ECOLOGICAL INFORMATION

General information:

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

Classification of water endangerment:

WGK=1 (slightly polluting substance).

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Substance: Waste is hazardous and to be treated as controlled waste. Product must be disposed of as special waste after consultation with local waste authorities and the disposal company in a suitable and licensed facility.

Packaging: Contaminated packaging should be emptied optimally and after appropriate professional cleaning may be taken for re-use. Packaging that cannot be cleaned should be disposed of professionally. Do not puncture or incinerate, even when empty. Contaminated rags and the like must be discarded into designated a fireproof bucket.

14. TRANSPORT INFORMATION

UN proper shipping name:

Land Transport ADR/GGVSEB	UN/Germany UN 1247	METHYL METHACRYLATE MONOMER MONOMER, STABILISED, Class 3, Group II, Tunnel restriction code D/E Hazard no. 339
Land Transport RID/GGVSEB	UN 1247	METHYL METHACRYLATE MONOMER MONOMER, STABILISED, Class 3, Group II Hazard no. 339
Inland Waterway Transport ADNR/GGVSEB	UN 1247	METHYL METHACRYLATE MONOMER MONOMER, STABILISED, Class 3, Group II
Shipment by Sea IMDG/GGVSee	UN 1247	METHYL METHACRYLATE MONOMER MONOMER, STABILISED, Class 3, Group II EmS F-E, S-D Marine pollutant No
Air Transport ICAO/IATA	UN 1247	METHYL METHACRYLATE MONOMER MONOMER, STABILISED, Class 3, Group II

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.

16. FURTHER INFORMATION

The substance is normally supplied in a stabilised form.

If the permissible storage period and/or storage temperature is noticeably exceeded, the substance may polymerise with heat evolution.

The instructions given here are valid only for the substance as supplied, not for derivatives resulting from its use.

The data given above covers exclusively the safety requirements of the product(s) and is based on our current knowledge and experience. It does not signify any warranty with regards to the products properties. This product is only supplied for specific uses in dentistry and must be used in accordance with the directions for use.