



1. Identification of the substance/mixture and of the Company/undertaking:

1.1 Product identifier:

Product Name: Gingival Barrier

1.2 Relevant identified use:

Relevant use: Dental professional use: For tissue isolation by dental professionals.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

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2. Hazard Identification

Classification of the substance/mixture:

Signal word: WARNING:



GHS Classification:
Skin Sens. 1



2. Hazard Identification

Hazard statements:

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing dust/fume/gas/mist/vapour/spray..
P272 Contaminated work clothing should not be allowed out of the workspace.
P280 Wear protective gloves.
P102 Keep out of reach of children.
P103 Read instructions for use before use.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 For specific treatment, refer to First Aid Instructions.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant

Other:

Product may cause irritation to the skin, eye and mucous membrane.
Ingestion of unpolymerised material may cause gastric irritation.
In isolated cases, contact allergies have been reported with acrylic resins. Anyone with known history of resin allergies are advised to seek the advice of a specialist before use.

3. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Acrylic monomer	-	75-85.0

Hazard classification:

Skin Sens 1: H317.

4. First Aid Measures

Eye (contact): Flush opened eye with running water for at least 5 minutes. Seek medical attention if irritation occurs.

Skin (contact): Remove contaminated clothing. Wash skin with soap and water. In case of allergic reaction, seek medical attention.

Ingestion: Seek medical attention.

Inhalation: None expected.

Most important effects, acute and delayed:

The most important known symptoms and effects are described in section 2 and/or in section 11.

Indication of any immediate medical attention and special treatment needed:

No data available.



5. Fire Fighting Measures

Suitable extinguishing media:	Sand, chemical foam, carbon dioxide, dry chemicals.
Unusual Fire and Explosion Hazards:	Heat can cause polymerization with rapid release of energy which may melt the container.
Unsuitable extinguishing media:	No data available.
Specific hazards arising from the mixture:	Slight fire hazard when exposed to heat or flame.
Special protective equipment:	No special measures required for small quantity (less than 1 kg). For large quantity, wear approved respirator and protective gear. Use water spray to cool container.
Advice for firefighters:	Wear self contained breathing apparatus for fire fighting if necessary.

6. Accidental Release Measures

Personal precautions:	Not required.
Environmental precautions:	Prevent any spillage from entering waterways, drains or sewage system.
Methods for cleaning and containment of spills:	Contain with absorbent material (e.g. sand, diatomaceous earth). Scoop up bulk material and transfer to containers for disposal in accordance with local regulations for hazardous waste.
Removal of ignition sources, provision of sufficient ventilation, control of dust:	Not expected

7. Handling and storage

<u>Precautions for safe handling:</u>	Replace caps immediately after use. For use by trained dental professionals.
<u>Conditions for safe storage, including any biocompatibilities:</u>	Store in a cool place at temperatures between 10°C and 25°C (50° - 77°F). Keep out of direct light.
Specific end use:	Apart from the use mentioned in section 1.2, there are no other uses for the product.



8. Exposure controls and personal protection

Control parameters:

Occupational Exposure Limits: We are not aware of any national exposure limit.

Exposure controls:

Respiratory protection: None required under normal conditions of use.

Hand protection: Rubber, latex or PVC gloves.

Eye protection: Not absolutely necessary

General safety and hygiene measures: Follow good housekeeping practices and good industrial hygiene in handling this material. Remove any naked lights or strong heat sources.

9. Physical and chemical properties

Appearance: Blue coloured viscous / flowable paste.

Odour: Ester like.

Boiling point: Gel before boiling.

Melting point: Not established.

Specific gravity: 1-2

Flash point: Not established.

Flammable: Not established.

Autoflammability: Do not self ignite.

Explosive properties: Do not present an explosion hazard.

Oxidizing properties: Not established.

Vapour pressure (@ 20°C): 0 mbar.

Relative density: Not established.

Solubility: Insoluble in water.

Auto-ignition temperature: Not established.

Decomposition temperature: Not established.

pH: Not established.



10. Stability and Reactivity

Chemical Stability:	Stable under normal conditions.
Conditions to avoid:	Avoid heat, ignition sources, aging, contamination and intense visible light.
Materials to avoid:	Free radical formers, e.g. peroxides, reducing substances and / or heavy metals ions.
Hazardous decomposition products:	None under normal conditions. Oxides of carbon when burned.
Hazardous reactivity (polymerization):	Heat and intense light can cause polymerization. Spontaneous polymerization may occur in the presence of radical formers. May polymerize under these conditions with heat evolution.

11. Toxicological information

Acute toxicity:	May be sensitising to skin.
Urethane dimethacrylate CAS 72869-86-4:	Oral (rat) LD50 > 2000mg/kg
Triethylene glycol dimethacrylate CAS 109-16-0:	Oral (rat) LD50 10837mg/kg; Oral (mouse): LD50 10750 mg/kg. Nil irritation reported.
Serious eye damage/irritation:	May be irritating to eyes.
Skin corrosion/irritation:	Possible skin irritant.
Respiratory or skin sensitisation:	In some cases contact allergies have been reported. No effects expected by inhalation.
Inhalation:	None expected.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. (IARC: International Agency for Research on Cancer, by the World Health Organisation (WHO)).
Reproductive toxicity:	No data available.
Specific target organ toxicity – single exposure:	May cause irritation to eyes, skin and inhalation.
Specific target organ toxicity – repeated exposure:	No data available.
Aspiration hazard:	No data available.



12. Ecological information

Self assessment:	Slightly hazardous for water. Do not allow large quantities to reach sewage system and waterways.
Ecotoxicity:	No data available.
Persistence and biodegradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and VPvB assessment:	PBT/VPvB assessment not available as chemical safety assessment not required/not conducted.
Other adverse effects:	No data available.

13. Disposal considerations

Dispose of in accordance with local official regulations.

Contaminated packaging: Dispose of contaminated packaging as hazardous waste in accordance with local official regulations.

14. Transport information

Not classified as Dangerous Goods for air, sea, rail or road transport.

15. Regulatory information

This product is regulated by: TGA
Medical Devices Directive 93/42/EEC
FDA
National regulations.

16. Other information

The information provided herein is given in good faith, but no warranty expressed or implied is made.

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