



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

1.1 Product identifier:

Product Identifier: Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura and LC Opaquer.

1.2 Relevant identified use:

Relevant use:

Professional dental use: For filling of cavitated teeth 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, hazard statement, precautionary statements:

Products 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.

2. Hazard Identification

SIGNAL WORD:

WARNING:



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.

Hazard statements:

H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapour/spray.
P271	Use outdoors or in a well ventilated area.
P264	Wash skin thoroughly after handling.
P271	Use in a well ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/ eye protection/ face protection.
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
P321	Specific treatment, refer to package insert.
P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P363	Wash contaminated clothing before reuse.
P305, P351, P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTRE or doctor/physician if you well.
P333 + P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before re-use.

Storage:

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.



Disposal:

P501

Dispose of contents/ container to an approved waste disposal plant

3. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Acrylic monomers	72869-86-4, 109-16-0, 24448-20-2	6.0 – 46.0

Classification - Skin Irrit. 2; Skin Sens. 1, Eye Irrit. 2; STOT SE 3 (Resp); H315, H317, H319, H335.

4. First Aid Measures

Eye (contact): Flush opened eye with running water for at least 15 minutes. Remove contact lenses if present and easy to do. If eye irritation persists, seek medical attention.

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

Ingestion: Seek medical attention.

Inhalation: If any respiratory irritation, remove victim to fresh air and seek medical attention if irritation persists or if feeling unwell.

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: No data available.

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 and full protective gear for fire fighting if necessary.

6. Accidental Release Measures

Personal precautions: Wear protective gloves and eyewear.

Environmental precautions: Prevent any spillage from entering waterways, drains or sewage system.

Methods for cleaning up: Scoop up bulk material and transfer to containers for disposal.

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, and control of dust: Not expected.

7. Handling and storage

Precautions for safe handling: Replace caps immediately after use.

Conditions for safe storage, including any biocompatibilities:

25°C Store in a cool place at temperatures between 10°C and (50° - 77°F). Keep out of direct light.

8. Exposure controls and personal protection

Respiratory protection: None required under normal conditions of use. Avoid breathing product.

Hand protection: Rubber, latex or PVC gloves.

Eye protection: Not absolutely necessary however avoid exposure with eyes as product is irritating.

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:	Tooth coloured viscous / flowable paste.
Odour:	Ester like.
Boiling point:	Gel before boiling.
Melting point:	Not established.
Specific gravity:	1.5 - 2.0
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.
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:	Irritating to skin, eye and mucous membrane.
Serious eye damage/irritation:	May cause irritation due to foreign body reaction.
Skin corrosion/irritation:	Possible skin irritant.
Respiratory or skin sensitisation:	Possible respiratory irritant. No sensitizing effect known. In isolated cases contact allergies have been reported.
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

Glacier, Wave, Wave MV, Wave HV, Rok, Ice, Aura and LC Opaquer are not classified as Dangerous Goods for air, sea, rail or road transport.

15. Regulatory information

These products are regulated by: TGA
Medical Devices 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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Department issuing SDS: Research and Development

Contact: R&D Director



SAFETY DATA SHEET [according to GHS]

**Product: GLACIER; WAVE, WAVE MV, WAVE HV, ROK, ICE, LUNA, AURA & LC
OPAQUER**

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