

SAFETY DATA SHEETS

This SDS packet was issued with item:

070351817

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070351809 070351825 070351833 070356261 070826834 070826842 070826867 070826875 070826883 070826891
070826933 070826941 070826958 070826966 070869073 076203004 076203012 076203020 076203038 076203046
076203053 076203061 076203079 076203087 076203095 076203103 076203111 076203129 076203137 076203145
076203152 076203160 076203178 076203244 076203251 076203269 076203277 076203285 076203293 076203301
076203319 076203327 076203335 076203343 076203350 076203368 076203376 076203384 076203392 076203400
076203418 076207997 076208003 076208011 076208029 076208037 076208045 076208052 076208060 076208169
076208177 076208185 076208193 076208201 076319503 076319545 076319552 076319560 076319578 076319586
076319594 076319602 076319610 076319628 076319636 076319644 076319651 076319669 076319677 076319719
076319727 076319735 076319743 076319750 076319768 076319776 076319784 076319792 076319842 076319859
076320105 076320154 076320162 076320196 076320212 076320220 076320238 076320246 076341002 076341010
076341028 076341036 076341044 076341051 076341069 076341077 076341085 076341093 076341101 076341119
076341127 076341135 076341143 076341150 076341168 076341176 076341184 076341192 076341200 076341218
076341226 076341390 076341408 076341416 076341424 076341432 076341440 076341457 076341473 076341507
076341531 076341549 076341556 076341564 076341572 076341580 076341598 076341614 076341648 076341671
076372502 076372510 076372528 076372536 076372650 076372668 076372676 076372684 076372692 076372718
076372726 076372734 076372742 076372767 076372775 076372932 076372940 076372957 076373401 076373468
076373476 076373484 076373492 076373500 076373518 076373526 076373534 076373559 076373567
076373575 076373583 076373617 076373625 076373633 076373641 076373658 076373666 076373682



1. Substance / Preparation and Company name

Product Name: Glacier; Wave; Wave MV; Wave HV; ROK, ICE and LC Opaquer

Recommended use: For filling of cavitated teeth by dental professionals.

Manufacturer / Supplier

SDI Limited
3-13 Brunsdon Street, Bayswater
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+55 11 3092 7100 (Business Hours)

Emergency contact number: +61 3 8727 7111

2. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Acrylic monomer	-	18.0 – 40.0
Balance ingredient (non-hazardous)		60.0 – 82.0

3. Hazard Identification

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.

Risk phrases - **36/37/38:** Irritating to eyes, respiratory system and skin.

Safety phrases - **26/28:** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with soap and water.

- **3/15/16:** Keep in a cool place, away from heat and sources of ignition.

- **2:** Keep out of reach of children.



4. First Aid Measures

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

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.
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.

6. Accidental Release Measures

Personal precautions:	Not required.
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.

7. Handling and storage

Handling

Replace caps immediately after use.

Storage

Storage by the end user (Dental Clinic) is recommended to be at temperatures between 10° - 25°C (50° - 77°F) and should be kept away from direct sunlight.

Distribution

During distribution, to our customers, this product can be transported in non-refrigerated conditions between 15° to 25° C. This product can also withstand temperatures up to 40° C for short periods (2 to 3 days) and intermittent peaks up to 50°C.



8. Exposure controls and personal protection

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:	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.



10. Stability and Reactivity

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 irritating to skin, eye and mucous membrane.
Sensitization:	No sensitizing effect known. In isolated cases contact allergies have been reported.
Inhalation:	None expected.

12. Ecological information

Self assessment:	Slightly hazardous for water. Do not allow large quantities to reach sewage system and waterways.
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13. Disposal considerations

Dispose of in accordance with local official regulations.

14. Transport information

Glacier, Wave, Wave MV, Wave HV, Rok, Ice 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.

Prepared by: SDI Limited
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+61 3 8727 7111

Department issuing MSDS: Research and Development
Contact: Operations Director



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:

SDI Limited
3-13 Brunsdon Street, Bayswater
Victoria, 3153, Australia

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2. Hazard Identification

Classification of the substance/mixture:

SIGNAL WORD:

WARNING:



GHS classification:

Skin sensitisation (Category 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 workplace.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

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

P321 Specific treatment, refer to package insert.

P363 Wash contaminated clothing before reuse.

P333 + P313 If skin irritation occurs: Get medical advice/attention.

Disposal:

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

Other information: Ingestion of unpolymerised material may cause gastric irritation

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 Sens. 1; H317.

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:

Store in a cool place at temperatures between 10°C and 25°C (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.



8. Exposure controls and personal protection

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
