

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

OPAQUER

Date / Revised: 12.08.2015 **Revision: 11**

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

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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 sensitisation (Category 1)

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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

Composition: CAS No. Wt. %

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.

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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

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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

<u>Precautions for safe handling:</u> 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

 $(50^{\circ} - 77^{\circ}F)$. 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.

9.

SAFETY DATA SHEET [according to GHS]

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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

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heat sources.

Physical and chemical properties

Tooth coloured viscous / flowable paste. Appearance:

Odour: Ester like.

Gel before boiling. Boiling point:

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.

Not established. Decomposition temperature: Not established. pH:

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.

polymerize under these conditions with heat evolution.

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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.

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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 biodegradeability: 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.

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13. Disposal considerations

Dispose of in accordance with local official regulations.

Contaminated packaging: Dispose of

Dispose of contaminated packaging as hazardous waste in accordance

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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

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