



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

1.1 Product identifier:

Product Name: Soothe

1.2 Relevant identified use:

Relevant use: For the desensitising of sensitive teeth.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

SDI Limited
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2. Hazard Identification

Classification of the substance/mixture: Not classified as hazardous according to GHS.

3. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>	<u>EC No</u>	<u>Index No.</u>
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Non-hazardous ingredients	-	-	-	-
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(Ingredients not classified as hazardous according to the GHS cut-off values/concentration limits.)



4. First Aid Measures

Eye (contact): Flush opened eye with running water for 15 minutes. Seek medical attention.

Skin (contact): Wash skin with plenty of water.

Ingestion: Seek medical attention if large dose is ingested.

Inhalation: Not expected. If feeling unwell, remove to fresh air.

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: Water spray, dry chemical, carbon dioxide, protein type air foams.

Unusual Fire and Explosion Hazards: Heat may generate irritating vapours, e.g. CO₂.

Unsuitable extinguishing media: No data available.

Specific hazards arising from the mixture: No data available.

Special protective equipment: Wear approved respirator and protective gear if necessary. Use spray to cool containers.

6. Accidental Release Measures

Personal precautions: Avoid getting into eyes.

Environmental precautions: Biodegradable.

Methods for cleaning up: Wipe up with cloth and water. For larger 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.

Advice on how to contain spill (eg. Bundling, covering of drains, capping procedures):

- Not expected



7. Handling and storage

Precautions for safe handling: Store sealed containers away from heat and light.

Conditions for safe storage, including any biocompatibilities:

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 / personal protection

Respiratory protection: Not applicable.

Hand protection: Rubber or PVC gloves.

Eye protection: Safety glasses, goggles or face shield.

General safety and hygiene measures: Follow good housekeeping practices and good industrial hygiene in handling this material.

9. Physical and chemical properties

Appearance: Clear gel

Odour: Spearmint

Boiling point: Not applicable

Melting point: Not applicable

Specific gravity: 1.0

pH 7.0

Flash point: Not applicable

Flammable: Not flammable

Autoflammability: Does not self-ignite

Explosive properties: Does not present an explosion hazard

Oxidising properties: Not an oxidiser

Vapour pressure (@ 20°C: Not established

Solubility: Soluble in water

Decomposition temperature: Not established



10. Stability and Reactivity

Chemical Stability:	Stable under normal conditions.
Conditions to avoid:	Combustibles and open flame.
Materials to avoid:	Metals, strong bases and organic solvents.
Hazardous decomposition products:	None under normal conditions.
Hazardous reactivity (polymerization):	Will not occur.

11. Toxicological information

Acute toxicity: Sodium fluoride:	Oral LD50 (rat): 31mg/kg; Oral LD50 (mice): 44mg/kg
Acute toxicity:	Not expected. May be irritating to skin, eye and mucous membrane.
Serious eye damage/irritation:	May be an irritant.
Skin corrosion/irritation:	Not expected to be an irritant.
Ingestion:	Small doses do not pose to be a health risk. Higher doses due to fluoride dosage ingestion.
Respiratory or skin sensitisation:	Not applicable.
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:	Not hazardous. Do not allow large quantities to reach sewage systems 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

This product is not considered to be a dangerous good within the meaning of transportation regulations.

15. Regulatory information

This product is regulated by: TGA
Medical Devices Directive 93/42/EEC
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
