

SAFETY DATA SHEETS

This SDS packet was issued with item:

076316129

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).

076316103 076316111 076316137 076316145 076320501 076320550 076372924



1. Substance / Preparation and Company name

Product Name: Conseal-Clear, Conseal-Light Grey, Conseal F (White)

Recommended use: For the protection of pits and fissures.

Manufacturer / Supplier

SDI Limited
3-13 Brunsdon Street, Bayswater
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Rua Dr. Virgílio de Carvalho Pinto, 612
Pinheiros, São Paulo, 05415-020
Brasil

Telephone:

+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>
Conseal-Clear		
Acrylic monomer	-	100.0
Conseal-Light Grey		
Acrylic monomer	-	80.0
Balance ingredient (non-hazardous)		20.0
Conseal F (White)		
Acrylic monomer	-	93.0
Balance ingredient (non-hazardous)		7.0



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 advise 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.

5. Fire Fighting Measures

Suitable extinguishing media: Dry powder, vapourizing liquid or foam extinguisher.

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. 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: Mop up spillage with absorbance paper/cloth soaked in ethanol/acetone.



7. Handling and storage

Handling

Replace caps immediately after use.

Storage

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.
Hand protection:	Rubber, latex 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. Remove any naked lights or strong heat sources.

9. Physical and chemical properties

Appearance:	Clear, pale yellow liquid - Conseal-Clear . Tooth coloured semi-translucent liquid - Conseal-Light Grey White liquid - Conseal F (White) .
Odour:	Ester like.
Boiling point:	Gel before boiling.
Melting point:	Not established.
Specific gravity:	1.1 - 1.2
Flash point:	Not established.
Flammable:	Not established.
Autoflammability:	Do not self ignite at room temperature.
Explosive properties:	Do not present an explosion hazard.
Oxidizing properties:	Not established.
Vapour pressure (@ 20°C):	Not established.
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.



10. Stability and Reactivity (Cont'd)

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.

11. Toxicological information

Acute toxicity: Irritating to skin, eye and mucous membrane.

Sensitization: No sensitizing effect known. In isolated cases contact allergies have been reported.

12. Ecological information

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

13. Disposal considerations

Dispose of in accordance with local official regulations.

14. Transport information

Conseal-Clear, Conseal-Light Grey and Conseal F (White) are not classified as Dangerous Goods for air, sea, rail and road transport.

15. Regulatory information

These products are 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.

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

Phone Number:
+61 3 8727 7111

Department issuing MSDS: Research and Development
Contact: Operations Director

**SAFETY DATA SHEET** [according to GHS]**Product:** CONSEAL- Clear, CONSEAL- Light Grey, CONSEAL F (WHITE)**Date / Revised:** 02.02.2015**Page 1 of 7****Revision:** 6**1. Identification of the substance/mixture and of the Company/undertaking:****1.1** Product identifier:

Product Name: Conseal-Clear, Conseal-Light Grey, Conseal F (White)

1.2 Relevant identified use:

Dental professional use: For the protection of pits and fissures.

1.3 Details of the supplier of the Safety Data Sheet:**Manufacturer / Supplier**SDI Limited
3-13 Brunsdon Street, Bayswater
Victoria, 3153, AustraliaSDI (North America) Inc.
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Emergency contact number: +61 3 8727 7111Email: ray.cahill@sdi.com.au (Technical Director, SDI Limited)**2. Hazard Identification**

Classification of the substance/mixture:

SIGNAL WORD: WARNING

GHS Classification:



Skin Sens. 1

2. Hazard Identification

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:

H317 May cause an allergic skin reaction.

Prevention:

P261 Avoid breathing vapour.
P272 Contaminated work clothing should not be allowed out of the workplace.
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 occurs,: Get medical advice/attention.
P321 Specific treatment- see product Instructions for Use.
P363 Wash contaminated clothing before reuse.

Disposal:

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

Other: Product may be irritating to skin, eye and mucous membrane. Ingestion of unpolymerised material may cause gastric irritation. Anyone with known resin allergies must not use this product without consulting a specialist.

3. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Conseal-Clear		
Acrylic monomer	-	100.0
Conseal-Light Grey		
Acrylic monomer	-	80.0
Balance ingredient (non-hazardous)		20.0
Conseal F (White)		
Acrylic monomer	-	93.0
Balance ingredient (non-hazardous)		7.0

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.
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. If feeling unwell, remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or doctor/physician if still 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:	Dry powder, vapourizing liquid or foam extinguisher.
Unsuitable extinguishing media:	No data available.
Specific hazards arising from the mixture:	Combustible. Slight fire hazard when exposed to heat or flame.
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.
Advice for firefighters:	Wear self contained breathing apparatus for fire fighting if necessary.

6. Accidental Release Measures

Personal precautions:	Not required.
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Environmental precautions:	Prevent any spillage from entering waterways, drains or sewage system.
Methods for cleaning up and containment:	Mop up spillage with absorbent paper/cloth soaked in ethanol/acetone. Dispose of in accordance with local regulations.
Removal of ignition sources:	Eliminate sources of ignition.

7. Handling and storage

Precautions for safe handling: Replace caps immediately after use. For use by trained dental professionals only.

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.

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: Safety glasses, goggles or face shield.

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: **Conseal-Clear** -Clear, pale yellow liquid; **Conseal-Light Grey** - Tooth coloured semi-translucent liquid; **Conseal F (White)** - White liquid.

Odour: Ester like.

Boiling point: Gel before boiling.

Melting point: Not established.

Specific gravity: 1.1 - 1.2

Flash point: Not established.

Flammable: Not established.

Autoflammability: Do not self ignite at room temperature.

Explosive properties: Do not present an explosion hazard.

Oxidizing properties: Not established.

Vapour pressure (@ 20°C): Not established.

Relative density: Not established.



Solubility:	Insoluble in water.
Auto-ignition temperature:	Not established.
Decomposition temperature:	Not established.
Initial boiling point and boiling range:	Not established.
pH:	Not established.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under normal conditions.
Possibility of hazardous reactions:	No data available.
Incompatible materials:	Free radical formers, e.g. peroxides, reducing substances and / or heavy metals ions.
Conditions to avoid:	Avoid heat, ignition sources, aging, contamination and intense visible light. Heat and intense light can cause polymerization.
Hazardous decomposition products:	None under normal conditions; oxides of carbon when burned.

11. Toxicological information

Acute toxicity:	May be skin sensitising.
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:	Skin irritant.
Respiratory or skin sensitisation:	In isolated cases contact allergies have been reported. Not respiratory sensitiser.
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 (such as hazardous to ozone layer):	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.
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14. Transport information

Conseal-Clear, Conseal-Light Grey and Conseal F (White) are not classified as Dangerous Goods for air, sea, rail and road transport.

15. Regulatory information

These products are regulated by:	TGA Medical Devices Directive 93/42/EEC FDA National regulations for medical devices
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16. Other information

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



SAFETY DATA SHEET [according to GHS]

Product: CONSEAL- Clear, CONSEAL- Light Grey, CONSEAL F (WHITE)

Date / Revised: 02.02.2015

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Revision: 6

Prepared by: SDI Limited
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Phone Number:
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Date of preparation/revision: 2nd February 2015

Department issuing SDS: Research and Development

Contact: R&D Director
