SAFETY DATA SHEETS

This SDS packet was issued with item:

076316103

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).

076316111 076316129 076316137 076316145 076320501 076320550 076372924

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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 SDI Inc.

3-13 Brunsdon Street, Bayswater 729 N.Route 83, Suite 315 Victoria, 3153, Australia Bensenville 60106 IL, USA

<u>Telephone</u>: <u>Telephone</u>:

+61 3 8727 7111 (Business hours) 630 238 8300 (Business hours)

Southern Dental Industries Ltd

Block 8, St Johns Court

Swords Road

SDI Brasil Indústria e Comércio Ltda
Rua Dr. Virgílio de Carvalho Pinto, 612
Pinheiros, São Paulo, 05415-020

Santry, Dublin 9, Ireland Brasil

<u>Telephone</u>: <u>Telephone</u>:

+353 1 886 9577 (Business Hours) +55 11 3092 7100 (Business Hours)

Emergency contact number: +61 3 8727 7111

2. Composition / Information on ingredients

Balance ingredient (non-hazardous)

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

7.0

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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.

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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.

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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 **Phone Number:** +61 3 8727 7111

3-13 Brunsdon Street, Bayswater

Victoria, 3153, Australia

Department issuing MSDS: Research and Development

Contact: Operations Director

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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, Australia

Telephone:

+61 3 8727 7111 (Business hours)

Southern Dental Industries Ltd Block 8, St Johns Court Swords Road

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1279 Hamilton Parkway

Itasca, IL 60143, USA

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SDI Brasil Indústria e Comércio Ltda

Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, São Paulo, 05415-020

2. Hazard Identification

Classification of the substance/mixture:

SIGNAL WORD: WARNING



GHS Classification:

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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.

P102 Reep 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.
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 un-

polymerised material may cause gastric irritation. Anyone with known resin allergies

14/4 0/

must not use this product without consulting a specialist.

CACNI

3. Composition / Information on ingredients

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

Hazard Classification:

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

Date / Revised: 02.02.2015 Revision: 6

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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

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

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Solubility: Insoluble in water. Auto-ignition temperature: Not established. Decomposition temperature: Not established.

Initial boiling point and

Not established. boiling range: Not established. pH:

10. Stability and Reactivity

Reactivity: No data available.

Stable under normal conditions. Chemical Stability:

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.

No data available. Germ cell mutagenicity:

IARC: No component of this product present at levels Carcinogenicity:

> 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)).

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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 (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.

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

16. Other information

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

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Revision: 6

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2nd February 2015 Date of preparation/revision:

Department issuing SDS: Research and Development

Contact: R&D Director

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