

SAFETY DATA SHEETS

This SDS packet was issued with item:

076207005

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).

076207013 076207021 076207039 076207047 076207054 076207062 076209902 076209910 076209928 076209936

076209944 076209951 076209969



1. Substance / Preparation and Company Name

Product Name: seT Capsules and seT PP Syringes

Recommended use: Cementing of composite, ceramic and metallic indirect restorations.

Manufacturer / Supplier

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

SDI Inc.
729 N.Route 83, Suite 315
Bensenville 60106 IL, USA

Telephone:

+61 3 8727 7111 (Business hours)

Telephone:

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Southern Dental Industries Ltd
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Swords Road
Santry, Dublin 9, Ireland

SDI Brasil Indústria e Comércio Ltda
Rua Dr. Virgílio de Carvalho Pinto, 612
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Brasil

Telephone:

+353 1 886 9577 (Business Hours)

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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>
Fluoroaluminosilicate Glass	---	60-70
Urethane Dimethacrylate	72869-86-4	<20
Camphorquinone	10373-78-1	<1
Acidic Monomer	---	<20

3. Hazard Identification

Product is an irritant. Avoid contact with skin and eyes.

Risk Phrases:	36	Irritating to eyes.
	38	Irritating to skin.
Safety Phrases:	25	Avoid contact with eyes.
	26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
	28	After contact with skin, wash immediately with water and soap.

4. First Aid Measures

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

Skin (contact): Remove contaminated clothing. Wash skin with plenty of water. If irritation occurs seek medical attention.

Ingestion: Drink plenty of water. Seek medical attention if discomfort continues.



5. Fire Fighting Measures

Suitable Extinguishing Media: None required.
Unusual Fire and Explosion Hazards: None.
Special Protective Equipment: No special protective equipment required.

6. Accidental Release Measures

Personal Precautions: Do not get into eyes, on skin or clothing.
Environmental Precautions: Prevent product from entering drains, surface water or ground water.
Method for Cleaning Spills: Contain with absorbent material (e.g. sand, diatomaceous earth) and dispose of in accordance with regulations.

7. Handling and storage - seT

Handling

Store sealed containers away from heat and light.

Storage

Storage by the end user (Dental Clinic) is recommended to be at temperatures between 2° - 8°C (35° - 45°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.

Handling and storage – seT PP

Handling

Store sealed containers away from heat and light.

Storage

Storage by the end user (Dental Clinic) is recommended to be at temperatures between 2° - 25° C (35° - 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: None required under normal conditions of use.
Hand Protection: Latex or rubber gloves.
Eye Protection: Safety glasses or goggles
General Safety and Hygiene Measures: None



9. Physical and Chemical Properties

Appearance:	Slightly yellow liquid
Odour:	Slightly characteristic odour
Boiling Point:	Not available
Melting Point:	Not available
Specific Gravity:	2.0 g / cm ³
Flash Point:	Not applicable
Flammable:	Not flammable
Autoflammability:	Not applicable
Explosive Properties:	Does not present an explosion hazard
Oxidising Properties:	Not applicable
Vapour Pressure (@ 20°C):	Not applicable
Vapour Density:	<1.0
Solubility:	Not miscible

10. Stability and Reactivity

Stability:	Stable under normal conditions.
Conditions to Avoid:	Avoid excessive heat
Materials to Avoid:	None
Hazardous Decomposition Products:	None when used as directed
Hazardous Reactivity (Polymerization):	No hazardous reactions known

11. Toxicological Information

Acute Toxicity:	Contact with skin and eyes may cause irritation.
Eye (contact):	Irritating to eyes.
Skin (contact):	Possible skin irritant.
Inhalation (powder)	May be irritating.
Ingestion:	Irritation not likely in small amounts.

12. Ecological Information

Self-Assessment:	Not readily biodegradable. Avoid large quantities entering drains, surface water or ground water.
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13. Disposal Considerations

Dispose 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
FDA
National regulations

16. Other Information

Preparation of MSDS:

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

Phone Number:
+61 3 8727 7111

Version: 1

The information contained in the Material Safety Data Sheet is based on data considered to be accurate, however, no warranty is expressed or implied regarding the accuracy of the data or the results to be obtained from the use thereof.

Department issuing MSDS: Research and Development
Contact: Technical Manager - Polymers



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

1.1 Product identifier:

Product Name: seT Capsules and seT PP Syringes

1.2 Relevant identified use:

Recommended use:

Professional dental use: Cementing of composite, ceramic and metallic indirect restorations.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

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

SDI (North America) Inc.
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Telephone:

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Southern Dental Industries Ltd
Block 8, St Johns Court
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Rua Dr. Virgílio de Carvalho Pinto, 612
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Emergency contact number:

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Email: ray.cahill@sdi.com.au (Technical Director, SDI Limited)

2. Hazard Identification

Classification of the substance/mixture:

SIGNAL WORD: DANGER





2. Hazard Identification

GHS Classification:

Skin Corr 1B

Eye Dam. 1

STOT SE 3 (lungs)

Hazard statements:

- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H335 May cause respiratory irritation.

Prevention:

- P260 Do not breathe dusts or mists.
- P261 Avoid breathing dust/fume/gas/mist/vapour/spray.
- P264 Wash hands thoroughly after handling.
- P272 Contaminated work clothing should not be allowed out of the workspace.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response:

- P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
- P303+P361+P353 IF ON SKIN (or hair): Remove/take off immediately contaminated clothing. Rinse skin with water/shower.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 For specific treatment, refer to First Aid Instructions.
- P363 Wash contaminated clothing before reuse.
- P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P310 Immediately call a POISON CENTRE or doctor/physician.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage:

- P405 Store locked up.

Disposal

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

3. Composition / Information on Ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Fluoroaluminosilicate Glass	---	60-70
Urethane Dimethacrylate	72869-86-4	<20
Camphorquinone	10373-78-1	<1
Acidic Monomer	---	<20

Hazard Classification:

Skin Corr 1B; Eye Dam. 1; STOT SE 3 (lungs): H314; H318; H335.

4. First Aid Measures



Eye (contact): Flush opened eye with running water for 15 minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek immediate medical attention.

Skin (contact): Remove contaminated clothing. Wash skin with plenty of water. If irritation occurs seek medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting. Drink plenty of water. Seek medical attention.

Inhaled: None expected due to dosage. If feeling unwell, remove victim to fresh air and remain in a comfortable position. Seek medical attention if required,

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: Foam type.

Unusual Fire and Explosion Hazards: None.

Unsuitable extinguishing media: Unknown

Specific hazards arising from the mixture: No data available.

Special Protective Equipment: No special protective equipment required for small quantity. For large quantity, wear approved respirator and protective gear. Use water spray to cool.

Advice for firefighters: Wear self contained breathing apparatus for fire fighting if necessary.

6. Accidental Release Measures

Personal Precautions: Do not get into eyes, on skin or clothing.

Environmental Precautions: Prevent product from entering drains, surface water or ground water.

Method for Cleaning and containment of Spills: Contain with absorbent material (e.g. sand, diatomaceous earth) and dispose of 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 - seT



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 2° - 8°C (35° - 45°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.

Handling and storage – seT PP

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 2° - 25° C (35° - 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.

Specific end use:

Apart from the use mentioned in section 1.2, there are no other uses for the product.

8. Exposure Controls / 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. For nuisance exposures use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand/skin Protection: Latex or rubber gloves. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Wash and dry hands.

Eye Protection: Safety glasses or goggles

General Safety and Hygiene Measures: Follow good housekeeping practices and good industrial hygiene in handling this material.

9. Physical and Chemical Properties



Appearance:	Slightly yellow liquid
Odour:	Slightly characteristic odour
Boiling Point:	Not available
Melting Point:	Not available
Specific Gravity:	2.0 g / cm ³
Flash Point:	Not applicable
Flammable:	Not flammable
Autoflammability:	Not applicable
Explosive Properties:	Does not present an explosion hazard
Oxidising Properties:	Not applicable
Vapour Pressure (@ 20°C):	Not applicable
Vapour Density:	<1.0
Solubility:	Not miscible
Auto-ignition temperature:	Not established
Decomposition temperature:	Not established
pH:	Not established

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Conditions to Avoid:	Avoid excessive heat.
Hazardous Decomposition Products:	None when used as directed.
Hazardous Reactivity (Polymerization):	No hazardous reactions known.
Incompatible materials:	Reducing and oxidizing agents, peroxides and amines.

11. Toxicological Information

Acute Toxicity:	Contact with skin and eyes may is corrosive/causes eye damage.
Serious eye damage/irritation:	Damaging to eyes.
Skin corrosion/irritation:	Skin corrosive.
Respiratory or skin sensitisation:	May be irritating.
Ingestion:	Irritation not likely in small amounts.
Germ cell mutagenicity:	No data available.

11. Toxicological Information



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 readily biodegradable. Avoid large quantities entering drains, surface water or ground water.
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 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



FDA
National regulations

16. Other Information

Prepared by: SDI Limited
3-13 Brunsdon Street, Bayswater
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Date of preparation/revision: 2nd February 2015.

The information contained in the Safety Data Sheet is based on data considered to be accurate, however, no warranty is expressed or implied regarding the accuracy of the data or the results to be obtained from the use thereof.

Department issuing SDS: Research and Development

Contact: R&D Director
