Pulpdent Corporation

Safety Data Sheet

Trade Name: **SEAL-RITE™ PIT AND FISSURE SEALANT**

1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation

Seal-Rite Pit and Fissure Sealant

Seal-Rite Low Viscosity Pit and Fissure Sealant

1.2 Application / Use

Dental material for use by dental professional only.

1.2.2 SIC

851 Human health activity

1.2.3 Use Category

55

1.3 Manufacturer

**Pulpdent Corporation**

80 Oakland Street, P.O. Box 780

Watertown, MA 02472  USA

Telephone: 1 617 926-6666 / Fax: 1 617 926-6262

Email: Pulpdent@pulpdent.com

1.4 Emergency Telephone Number

1-800-535-5053 (24 Hour / USA)

1.5 Authorized European Representative

Advena Ltd.

Pure Offices, Plato Close

Warwick, CV34 6WE

United Kingdom

2.0 Hazards Identification

2.1 Classification

Irritant.

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
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</thead>
<tbody>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE</td>
<td>3</td>
<td>H335</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>1</td>
<td>H317</td>
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</table>

2.1.2 Classification according to Directive 67/548/EEC

Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)

2.2 GHS Label Elements

Hazard Pictograms

⚠️ Signal Word: **WARNING**

**Restricted to use by dental professional only.**

**Hazard Statements**

H319: Eye irritation. 2. May cause eye irritation.

H335: STOT SE. 3. May cause respiratory irritation.

H315: Skin irritation. 2. May cause skin irritation.

H317: Sensitization. 1. May cause an allergic skin reaction.

**Precautionary Statements**

P261: Avoid breathing vapor.

P280: Wear protective gloves and eye protection

P305+P351: If in eyes, rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

P333+P313: If irritation or rash occurs, get medical advice/attention.

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
Pulpdent Corporation

Safety Data Sheet
Trade Name: SEAL-RITE™ PIT AND FISSURE SEALANT

3.0 Composition

3.1 Chemical characterization of the preparation: Methacrylate ester monomers in a light-cured, glass-filled paste.

3.2 Hazardous ingredients

<table>
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<tr>
<th>CAS Number</th>
<th>Name of the Ingredient</th>
<th>Concentration</th>
<th>Classification per 67/548/EEC</th>
<th>Classification per Regulation (EC) No.1272/2008 (CLP)</th>
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</table>
| Proprietary | Uncured methacrylate ester monomers | 55-65% | Xi (Irritant), R36/37/38, R43 | Eye irritation, 2, H319
| | | | | STOT SE 3, H335
| | | | | Skin irritation, 2, H315
| | | | | Skin sensitization, 1, H317 |
| 112945-52-5 | Amorphous silica | 5% | Xi (Irritant), R36/37/38 | Eye irritation, 2, H319
| | | | | STOT SE 3, H335
| | | | | Skin irritation, 2, H315 |

4.0 First Aid Measures

4.1 General Information
May be irritating to eyes, respiratory system and skin. Prolonged or repeated contact with methacrylate may cause sensitization. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

4.2 Inhalation
Move to fresh air. If necessary, administer oxygen and/or artificial respiration and seek medical attention.

4.3 Skin Contact
Take off contaminated clothing. Wash skin thoroughly with soap and water.

4.4 Eye Contact
Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.

4.5 Ingestion
Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

4.6 Precautions for first responders
Ventilate the area. Wear eye and skin protection.

4.7 Information for physicians
Symptoms
Irritation or redness in eyes, throat or on skin.

Hazards
May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.

Treatment
As above under First Aid.

5.0 Fire Fighting Measures

5.1 Suitable extinguishing media
Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

5.2 Extinguishing media to avoid
Do not use direct water stream

5.3 Special exposure hazards in a fire
Heat may cause polymerization with rapid release of energy.

5.4 Special protective equipment for firefighters
Self-contained breathing apparatus.

6.0 Accidental Release Measures

6.1 Personal precautions.
Ventilate area. Wear safety glasses, gloves and lab coat.

6.2 Environmental precautions
Contain spilled material. Follow all government regulations.
6.3 Method for clean up
Absorb/wipe up spill with paper towels or cloths. Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

7.0 Handling and Storage
7.1 Handling
For use only by dental professionals trained in its use. Follow good hygiene practices. Remove applicator tip from syringe and cap container immediately after use. Keep light-cured materials shaded from intense light sources.

7.2 Storage
Store product tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, ignition sources, temperature extremes (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.

7.3 Specific uses
Dental material

8.0 Exposure Controls / Personal Protection
8.1 Exposure limit values
PEL: Not established. TLV: Not established.

8.2 Exposure controls
8.2.1 Occupational exposure controls
No special equipment required under normal conditions of use.

8.2.1.1 Respiratory protection
Good general ventilation is sufficient to control any airborne vapors.

8.2.1.2 Hand protection
No special requirements other than the usual surgical gloves.

8.2.1.3 Eye protection
No special requirements other than the usual safety glasses.

8.2.1.4 Skin protection
Good personal hygiene and safety practices; wearing a lab coat.

8.2.1.5 Other controls
Emergency eye wash fountain. Wash hands after use.

8.2.2 Environmental exposure controls
Cure material before disposing. To the best of our knowledge, cured material is inert. Follow all government regulations.

9.0 Physical and Chemical Properties
9.1 Appearance / Color
Off-white paste

9.1.1 Color / Physical state
Off-white paste

9.1.2 Odor
Faint, characteristic

9.2 Important health, safety and environmental information
9.2.1 pH
Not determined

9.2.2 Boiling point
Not determined

9.2.3 Flash point
Not determined

9.2.4 Flammability (solid, gas)
Not applicable

9.2.5 Explosive properties
Not applicable

9.2.6 Oxidizing properties
Not determined

9.2.7 Vapor pressure
< 1 mm Hg / 133 Pa / Id: B

9.2.8 Specific gravity
Seal-Rite: 1.550; Seal-Rite LV: 1.290

9.2.9 Solubility in water
Nil

9.2.10 Partition coefficient
Not determined
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<td>Stability and reactivity</td>
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## 16.0 Other information

| 16.1  | List of relevant R phrases | R36/37/38: Irritating to eyes, respiratory system and skin.  
R43: Sensitizing by skin contact |
|-------|-----------------------------|---------------------------------------------------------------------|
H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation.  
H315: Skin irritation. Hazard category 2.  
H317: Skin Sensitization. Hazard category 1. |
| 16.3  | Precautionary Statements    | P261: Avoid breathing vapor.  
P280: Wear protective gloves and eye protection  
P305+P351: If in eyes, rinse cautiously with water for several minutes.  
P337+P313: If eye irritation persists, get medical advice/attention.  
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P333+P313: If irritation or rash occurs, get medical advice/attention.  
P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F. |
| 16.4  | Restrictions on use         | Pulpdent products are to be sold to and used by dental professionals only. |
| 16.5  | Further information         | The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. |
| 16.6  | Sources of key data         | National Institute for Occupational Safety (NIOSH)  
US Occupational Safety and Health Administration (OSHA)  
| 16.7  | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |