# Safety Data Sheet

**Trade Name:** PULPDENT LIME-LITE

## 1.0 Commercial Product Name and Supplier

<table>
<thead>
<tr>
<th>1.1 Commercial product name / designation</th>
<th>Lime-Lite Light-cured Cavity Liner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 Application / Use</td>
<td>Dental material for use by dental professional only.</td>
</tr>
<tr>
<td>1.2.2 SIC</td>
<td>851 Human health activity</td>
</tr>
<tr>
<td>1.2.3 Use Category</td>
<td>55</td>
</tr>
<tr>
<td>1.3 Manufacturer</td>
<td>Pulpdent Corporation</td>
</tr>
<tr>
<td></td>
<td>80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</td>
</tr>
<tr>
<td></td>
<td>Telephone: 1 617 926-6666</td>
</tr>
<tr>
<td></td>
<td>Fax: 1 617 926-6262</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a></td>
</tr>
</tbody>
</table>

### 1.4 Emergency Telephone Number

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

### 1.5 Authorized European Representative

International Business Solutions Ltd.

54 Mayfield Ridge, Hatch Warren

Basingstoke, RG22 4RS UK

- Tel: 07989 407479 / Fax: 01256 350330
- Email: s.williams5@btconnect.co.uk

## 2.0 Hazards Identification

### 2.1 Classification

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</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>
</tr>
</tbody>
</table>

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

### 2.1.2 Classification according to Directive 67/548/EEC

(See SECTION 16 for full text of risk phrases)

### 2.2 GHS Label Elements

- **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.
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>
<thead>
<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.1278/2008 (CLP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary</td>
<td>Uncured methacrylate ester monomers</td>
<td>55-65%</td>
<td>Xi (Irritant), R36/37/38, R43</td>
<td>Eye irritation, 2, H319, STOT SE 3, H335, Skin irritation, 2, H315, Skin sensitization, 1, H317</td>
</tr>
</tbody>
</table>

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 for 15 minutes.

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 fire-fighters A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

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 or wipe up spill with suitable material (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 their use. Follow good hygiene practices. Do not smoke, eat or drink while using. Remove applicator tip from syringe and cap container immediately after use. Keep light-cured materials shaded from intense light sources.

7.2 Storage
Keep containers tightly closed. Store product in original container at cool room temperature (<25°C) and in a dry, well-ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature (>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 of this product in the quantity provided.

8.2.1.1 Respiratory protection
None required. Good general ventilation is sufficient to control any airborne vapors from uncured material.

8.2.1.2 Hand protection
No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.

8.2.1.3 Eye protection
No special requirements other than the usual safety glasses worn by dental staff.

8.2.1.4 Skin protection
No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.

8.2.1.5 Other controls
Emergency eye wash fountain should be available. 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

9.2 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
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9.2.5 Explosive properties Not applicable
9.2.6 Oxidizing properties Not determined
9.2.7 Vapor pressure < 1 mm Hg / 133 Pa / ld: B
9.2.8 Specific gravity 1.510
9.2.9 Solubility in water Nil
9.2.10 Partition coefficient Not determined
9.2.11 Viscosity Not determined
9.2.12 Vapor density > 1
9.2.13 Evaporation rate Not determined

### 10.0 Stability and reactivity

10.1 Conditions to avoid Temperature extremes (>27°C/80°F, <5°C/40°F), light.
10.2 Materials to avoid Reducing and oxidizing agents, peroxides, amines.
10.3 Hazardous decomposition products Under fire conditions, with amounts greater than in this product, hazardous polymerization may occur with heat buildup, release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4 Further information Polymerization will occur when light-cured material is exposed to direct light.

### 11.0 Toxicological information

11.1 Acute toxicity Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2 Irritation and corrosiveness May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.
11.3 Sensitization May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4 Sub-acute, sub-chronic and prolonged toxicity Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts of this material may cause eye and respiratory irritation.
11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity None known.
11.6 Empirical data None available.
11.7 Clinical experience Lime-Lite has been sold on the domestic and international market for more than 15 years. During that time there have been no reports of adverse events.

### 12.0 Ecological Information

12.1 Ecotoxicity To the best of our knowledge, polymerized material is inert. No other information is available.

### 13.0 Disposal Considerations

13.1 Regulations Polymerize before disposal. Follow all local and national government regulations in disposing material or contaminated packaging.
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## Trade Name: PULPDENT LIME-LITE

### 14.0 Transport Information

| 14.1 Restrictions | None. Not regulated. |

### 15.0 Regulatory Information

| 15.1 EU | Class IIA medical device under MDD 93/42/EEC. |
| 15.2 US FDA | Class II medical device |
| 15.3 Health Canada | Class III medical device |

### 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 |
| 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. |
| 16.7 Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |