This SDS packet was issued with item:
075912530

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075912415 075912423 075912431 075912449 075912456 075912464 075912472 075912514 075912522 075912548
075912555 075912563 075912571
Pulpdent Corporation
Material Safety Data Sheet: Tuff-Temp Temporary Crown and Bridge Material

IDENTITY
Tuff-Temp Temporary Crown and Bridge Material
Chemical Description: Glass-filled resin in two parts, base and catalyst, with photo-initiator and self-cure chemistry.
Product Use: Temporary crown and bridge material

SECTION I
Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472 USA

Date prepared: December 1, 2008

SECTION II - HAZARDOUS INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>CAS Number</th>
<th>PEL / TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncured methacrylate resins</td>
<td>-----------</td>
<td>Not established</td>
</tr>
<tr>
<td>Silica, amorphous</td>
<td>112945-52-5</td>
<td>6 mg/m³ / 10 mg/m³</td>
</tr>
</tbody>
</table>

DOT HAZARD CLASSIFICATION: None required
WHMIS CLASSIFICATION: D-2, Possible irritant
NFPA HMIS RATING: HEALTH: 1  FLAMMABILITY: 0  REACTIVITY: 1

SECTION II - PHYSICAL / CHEMICAL CHARACTERISTICS

- Light cure set time: 20 seconds
- Self-cure set time: 7 minutes
- Appearance: Two tooth-colored pastes, base and catalyst
- Odor: Slight, characteristic

SECTION IV - FIRE AND EXPLOSION HAZARD

- Flash point: Not established
- Auto-ignition temperature: Not established
- Flammable limits: Not established

Hazardous Combustion Products: Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Extinguishing Media: Carbon dioxide, dry chemical, alcohol foam or water fog. Water spray may be used to keep exposed containers cool.

Special Fire Fighting Procedures: A self-contained breathing apparatus should be worn by fire-fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

SECTION V - REACTIVITY DATA

- Stability: Stable
- Conditions to avoid: Intense light, temperature >100°F / 38°C, cross-contamination.
- Incompatibility: Reducing and oxidizing agents.
- Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen
- Hazardous Polymerization: None under normal conditions of use.
- Conditions to avoid: Strong light, temperature >100°F / 38°C, cross-contamination.
SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard in the small quantities present in this product and under normal conditions of use. Material may be irritating to eyes, mucous membranes or skin on contact.

Route of Exposure                   Signs and Symptoms
Inhalation                          May be irritating to mucous membranes.
Eye Contact                         May be irritating.
Skin Absorption                     Not applicable
Skin Contact                        Primary route of exposure, possibly irritating or sensitizing.
Ingestion                           None expected with this product in normal conditions of use. May be irritating to mucous membranes.

Summary of Chronic Hazards: May be sensitizing, especially with prolonged and/or repeated exposure.
Carcinogenicity                     Not known to be a carcinogen.
Teratogenicity, Mutagenicity, Reproductive Toxicity: None known

Emergency First Aid Procedures
Inhalation                          Move exposed person to fresh air. Seek medical care.
Eye contact                         Flush eyes with running water for 15+ minutes. Seek medical attention.
Ingestion                           Rinse mouth. Consult physician.
Skin contact                        Wash skin with soap and running water. Seek medical attention if irritation persists.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Handling/Storage Precautions: Avoid temperature extremes, strong light, cross-contamination, moisture.
Release or Spill: Wear gloves, safety glasses. Pick up with absorbent material (paper or cloth) and collect for suitable disposal.
Waste Disposal Method: Follow all government regulations.
Other Precautions: Wash hands after use.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: Not necessary under normal conditions of use of this product.
Ventilation: No special ventilation required under normal conditions of use of this product.
Protective Gloves: Recommended
Eye Protection: Safety glasses are recommended when normal conditions of use are anticipated. Chemical splash goggles should be worn whenever there is a possibility of splashing or contact.
Other Protective Clothing or Equipment: Emergency eye wash fountain should be close-by and maintained.
Work / Hygienic Practices: Wash hands after use.

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.
Safety Data Sheet
Trade Name: Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin

1.0 Commercial Product Name and Supplier

1.1 Commercial product name / designation
Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin
Tuff-Temp™ Provisional Add-On
Tuff-Temp™ Provisional Glaze

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

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]
Eye irritation
STOT SE
Skin irritation
Skin sensitization

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.
Safety Data Sheet
Trade Name: Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin

3.0 Composition

3.1 Chemical characterization of the preparation: Glass-filled methacrylate resins in a two-part, dual-cure 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.1272/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary</td>
<td>Uncured methacrylate resins</td>
<td>55-60%</td>
<td>Xi (Irritant), R 36/37/38 - 43</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317</td>
</tr>
<tr>
<td>112945-52-5</td>
<td>Silica, amorphous</td>
<td>5 %</td>
<td>Xi (Irritant), R 36/37/38</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information
May be irritating to eyes, mucous membranes or skin on contact. Avoid contact with eyes and skin. May cause sensitization by skin contact. 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. 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, mucous membranes 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
Self-contained breathing apparatus

6.0 Accidental Release Measures

6.1 Personal precautions.
Wear safety glasses, gloves and lab coat.
Safety Data Sheet

Trade Name: **Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin**

### 6.2 Environmental precautions
Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.

### 6.3 Method for clean up
Contain spilled material. Absorb or wipe up spill 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

<table>
<thead>
<tr>
<th>7.1 Handling</th>
<th>For use only by dental professionals. Follow good hygiene practices. Avoid direct, strong light sources, temperature extremes (&gt;27°C/80°F, &lt;5°C/40°F), contamination, cross contamination. Recap immediately after use.</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2 Storage</td>
<td>Store tightly capped in original container at cool room temperature (&lt;25°C). Avoid direct, strong light, sources of ignition, extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.</td>
</tr>
<tr>
<td>7.3 Specific uses</td>
<td>Provisional dental material</td>
</tr>
</tbody>
</table>

### 8.0 Exposure Controls / Personal Protection

<table>
<thead>
<tr>
<th>8.1 Exposure limit values</th>
<th>PEL: Not established. TLV: Not established.</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.2 Exposure controls</td>
<td></td>
</tr>
<tr>
<td>8.2.1 Occupational exposure controls</td>
<td>No special equipment required under normal conditions of use of this product in the quantity provided.</td>
</tr>
<tr>
<td>8.2.1.1 Respiratory protection</td>
<td>Good general ventilation is sufficient to control any airborne.</td>
</tr>
<tr>
<td>8.2.1.2 Hand protection</td>
<td>Surgical gloves</td>
</tr>
<tr>
<td>8.2.1.3 Eye protection</td>
<td>Safety glasses</td>
</tr>
<tr>
<td>8.2.1.4 Skin protection</td>
<td>Good personal hygiene and safety practices; wear a lab coat.</td>
</tr>
<tr>
<td>8.2.1.5 Other controls</td>
<td>Emergency eye wash fountain. Wash hands after use.</td>
</tr>
<tr>
<td>8.2.2 Environmental exposure controls</td>
<td>Cure material before disposing.</td>
</tr>
</tbody>
</table>

### 9.0 Physical and Chemical Properties

<table>
<thead>
<tr>
<th>9.1 Characteristics</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1.1 Appearance / Color / Physical state</td>
<td>Two pastes: tooth-colored base; off-white catalyst</td>
</tr>
<tr>
<td>9.1.2 Odor</td>
<td>Faint, characteristic</td>
</tr>
<tr>
<td>9.2 Important health, safety and environmental information</td>
<td></td>
</tr>
<tr>
<td>9.2.1 pH</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.2 Boiling point</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.3 Flash point</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.4 Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>9.2.5 Explosive properties</td>
<td>Not applicable</td>
</tr>
<tr>
<td>9.2.6 Oxidizing properties</td>
<td>Not determined</td>
</tr>
<tr>
<td>9.2.7 Vapor pressure</td>
<td>&lt; 1 mm Hg</td>
</tr>
</tbody>
</table>
Safety Data Sheet
Trade Name: Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin

9.2.8 Specific gravity 1.520
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 Not determined
9.2.13 Evaporation rate Not determined

10.0 Stability and reactivity
10.1 Conditions to avoid Temperature > 27°C / 80°F, light, cross-contamination of parts.
10.2 Materials to avoid Reducing and oxidizing agents, peroxides, amines.
10.3 Hazardous decomposition products Under fire conditions and with amounts greater than that supplied in this product, hazardous polymerization may occur with heat build-up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4 Further information Stable material if stored and used as directed. Polymerization will occur when light-sensitive 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 (more than in this product) may cause eye and respiratory irritation.
11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity None known
11.6 Empirical data Testing confirmed biocompatibility of Tuff-Temp Plus.
11.7 Clinical experience Tuff-Temp Plus has been on the market for more than four years with no reports of adverse events.

12.0 Ecological Information
12.1 Ecotoxicity Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.

13.0 Disposal Considerations
13.1 Regulations Follow all local and national government regulations in disposing material or contaminated packaging.

14.0 Transport Information
14.1 Restrictions None. Not regulated.
Safety Data Sheet

Trade Name: *Tuff-Temp™ Plus Provisional Veneer, Crown & Bridge Resin*

### 15.0 Regulatory Information

<table>
<thead>
<tr>
<th>15.1</th>
<th>EU Regulations</th>
<th>Class IIa medical device under MDD 93/42/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.2</td>
<td>US FDA</td>
<td>Class II medical device.</td>
</tr>
<tr>
<td>15.3</td>
<td>Health Canada</td>
<td>Class III medical device</td>
</tr>
</tbody>
</table>

### 16.0 Other information

<table>
<thead>
<tr>
<th>16.1</th>
<th>List of relevant R phrases</th>
<th>R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.</th>
</tr>
</thead>
<tbody>
<tr>
<td>16.4</td>
<td>Restrictions on use</td>
<td>To be sold to and used by dental professionals only.</td>
</tr>
<tr>
<td>16.5</td>
<td>Further information</td>
<td>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.</td>
</tr>
<tr>
<td>16.7</td>
<td>Information which has been added, deleted or revised.</td>
<td>This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, 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.</td>
</tr>
</tbody>
</table>