Safety Data Sheet

Trade Name: **EMBRACE™ Product Line**

### 1.0 Commercial Product Name and Supplier

#### 1.1 Commercial product name

- **Embrace™ WetBond™ Class V**
- **Embrace™ WetBond™ First Coat**
- **Embrace™ Esthetic Opaquer**
- **Embrace™ WetBond™ Pit & Fissure Sealant**
- **Embrace™ WetBond™ Pit & Fissure Sealant Low Fill**
- **Embrace™ WetBond™ Seal-n-Shine™**
- **Embrace™ WetBond™ Resin Cement**

**Codes**
- EMVA2, EMVA3.5, EMVB2, EMVD2
- EMFC
- EMO4, EMO5
- EMS, EMS3, EMSB, EMSW, EMS3W, EMSWB
- EMSWLF, EMSWLFB
- EMSNS, EMSNY
- EMCA, EMCAR, EMCAR2, EMCAR2, EMCM, EMCMR, EMCMR2,

**Application / Use**

Dental material for use by dental professional only.

#### 1.2 SIC

851 Human health activity

#### 1.3 Use Category

55

#### 1.4 Manufacturer

**Pulpdent Corporation**
80 Oakland Street
Watertown, MA 02472 USA

Telephone: 1 617 926-6666
Fax: 1 617 926-6262
Email: Pulpdent@pulpdent.com

#### 1.5 Emergency Telephone Number

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

#### 1.6 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]

<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>

##### 2.1.2 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.
Pulpdent Corporation

Safety Data Sheet

Trade Name: **EMBRACE™ Product Line**

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: Acrylate ester monomers in two-part, glass-filled, 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 acrylate ester monomers</td>
<td>55-60%</td>
<td>Irritant; Xi R 3637//38 - 43</td>
<td>Eye irritation, 2 Skin irritation, 2 Skin sensitization, 1</td>
</tr>
<tr>
<td>112945-52-5</td>
<td>Silica, amorphous</td>
<td>5 %</td>
<td>Irritant; Xi, R 36/37/38</td>
<td>Eye irritation, 2 STOT SE 3 Skin irritation, 2</td>
</tr>
<tr>
<td>7681-49-4</td>
<td>Sodium fluoride</td>
<td>&lt;1%</td>
<td>Harmful (Xn); R22-36/38</td>
<td>Acute toxicity, 4 Skin irritation, 2 Eye irritation, 2</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information
May be irritating to eyes, respiratory system and skin. Do not inhale vapors. 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 thoroughly with soap and water.

4.4 Eye Contact
Keep eyelids apart, 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, skin or sensitizing 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. Cool exposed containers with water spray to prevent polymerization under fire conditions.

6.0 Accidental Release Measures

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

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 with paper towels or cloths. Collect for disposal in a covered container. Wash spill area with alcohol or soap and water.

7.0 Handling and Storage

7.1 Handling  
For use only by dental professionals. Follow good hygiene practices. Avoid direct/strong light sources, temperature extremes (>27°C/80°F, <5°C/40°F), contamination and cross contamination. Recap immediately after use.

7.2 Storage  
Store product tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, sources of ignition and extremes of temperature. 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 restorative materials

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 will control airborne vapors from uncured material.

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 and wearing a lab coat should protect from 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.

9.0 Physical and Chemical Properties

9.1 Characteristics

9.1.1 Appearance /Color / Physical state  
Embrace Product Description

First Coat, Seal-n-Shine Thin, clear liquid

Esthetic Opaquer Opaque, thick paste: Bleach White, Off-White, Light Yellow, Pink, Dark Yellow

Pit and Fissure Sealant Natural tooth shade or off-white thin paste.

Pit and Fissure Sealant, Low Fill Off-white thin paste

Class V Tooth-colored paste.

Resin Cement: Two thin pastes: one white, one yellow.
### 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

#### 9.2.8 Specific gravity
- Embrace First Coat: 1.420
- Embrace Seal-n-Shine: 1.240
- Embrace Opaquer: 1.780
- Embrace Pit & Fissure Sealant: 1.575
- Embrace Pit & Fissure Sealant, Low Fill: 1.160
- Embrace Class V: 2.030
- Embrace Resin Cement: Low Viscosity: 1.660
- Embrace Resin Cement: Medium Viscosity: 1.400

#### 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 > 38°C, intense light, cross-contamination.

#### 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 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-cured material is exposed to direct light.

### 11.0 Toxicological information

#### 11.1 Acute toxicity
Not toxic. Minimal health hazard under normal conditions of use.

#### 11.2 Irritation and corrosiveness
May be irritating to eyes, respiratory tract, 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.
Safety Data Sheet

Trade Name: **EMBRACE™ Product Line**

11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity
None known

11.6 Empirical data
Not available

11.7 Clinical experience
Embrace products have been used safely and effectively by dentists in the US and internationally for more than 10 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.

15.0 Regulatory Information

15.1 EU
Class IIa medical devices under MDD 93/42/EEC.

15.2 US FDA
Class II medical devices.

15.3 Health Canada
Class II medical devices

16.0 Other information

16.1 List of relevant R phrases
R 36 / 37 / 38: Irritating to eyes, respiratory system and skin.
R 43: Sensitizing by skin contact.

16.2 Hazard Statements
H319: Eye irritation. Hazard category 2.
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.
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.

16.4 Restrictions on use
Embrace Product Line is to be sold to and used by dental professionals only.
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.

Sources of key data

National Institute for Occupational Safety (NIOSH)
US Occupational Safety and Health Administration (OSHA)

This Safety Data Sheet has been revised to meet the GHS SDS format and the requirements of 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.