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

Code

- EMVA2, EMVA3.5, EMVB2, EMVD2
- EMFC
- EMOK, EMO1, EMO2, EMO3, EMO4, EMO5
- EMS, EMS3, EMSB, EMSW, EMS3W, EMSWB
- EMSWLF, EMSWLFB
- EMSNS, EMSNY
- EMCA, EMCAR, EMCAR2, EMCM, EMCMR, EMCMR2,

1.2 Application / Use

Dental material for use by dental professional only.

1.3 Use Category

- 851 Human health activity
- 55

1.4 Manufacturer, Importer

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 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

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 (See SECTION 16 for full text of risk phrases)

Irritant; Xi; R 36/37/38 - 43

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.

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.1278/2008 (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, 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>Irritant; Xi, 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, respiratory system and skin. Avoid contact with eyes 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 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
Precautions for first responders
Ventilate the area. Wear eye and skin protection.

Information for physicians

Symptoms
Irritation or redness in eyes, throat or on skin.

Hazard
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 fire fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

6.0 Accidental Release Measures

6.1 Personal precautions.

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 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. Follow good hygiene practices. Do not smoke, eat or drink while using. Avoid direct / strong light sources, extremes of temperature (>27°C/80°F, <5°C/40°F), contamination, and cross contamination of two-part materials. Recap immediately after use.

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. 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 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.

9.0 Physical and Chemical Properties

9.1 Appearance

9.1.1 Color / Physical state

<table>
<thead>
<tr>
<th>Embrace Product</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Coat, Seal-n-Shine</td>
<td>Thin, clear liquid</td>
</tr>
<tr>
<td>Esthetic Opaquer</td>
<td>Opaque, thick paste</td>
</tr>
<tr>
<td>Bleach White, Off-White, Light Yellow, Pink or Dark Yellow</td>
<td></td>
</tr>
<tr>
<td>Pit and Fissure Sealant</td>
<td>Natural tooth shade or off-white thin paste.</td>
</tr>
<tr>
<td>Pit and Fissure Sealant, Low Fill</td>
<td>Off-white thin paste</td>
</tr>
<tr>
<td>Class V</td>
<td>Tooth-colored paste.</td>
</tr>
<tr>
<td>Resin Cement</td>
<td>Two thin pastes: one white, one yellow.</td>
</tr>
</tbody>
</table>

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 Stability and Reactivity

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.2.7</td>
<td>Vapor pressure &lt; (1\text{ mm Hg})</td>
</tr>
<tr>
<td>9.2.8</td>
<td>Specific gravity</td>
</tr>
<tr>
<td>9.2.9</td>
<td>Solubility in water Nil</td>
</tr>
<tr>
<td>9.2.10</td>
<td>Partition coefficient Not determined</td>
</tr>
<tr>
<td>9.2.11</td>
<td>Viscosity Not determined</td>
</tr>
<tr>
<td>9.2.12</td>
<td>Vapor density Not determined</td>
</tr>
<tr>
<td>9.2.13</td>
<td>Evaporation rate Not determined</td>
</tr>
</tbody>
</table>

### 10.0 Stability and Reactivity

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1</td>
<td>Conditions to avoid Temperature &gt; (38^\circ\text{C}), intense light, cross-contamination.</td>
</tr>
<tr>
<td>10.2</td>
<td>Materials to avoid Reducing and oxidizing agents, peroxides, amines.</td>
</tr>
<tr>
<td>10.3</td>
<td>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.</td>
</tr>
<tr>
<td>10.4</td>
<td>Further information Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.</td>
</tr>
</tbody>
</table>

### 11.0 Toxicological Information

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1</td>
<td>Acute toxicity Not toxic. Minimal health hazard in the quantity present in this product and under normal conditions of use.</td>
</tr>
<tr>
<td>11.2</td>
<td>Irritation and corrosiveness May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure.</td>
</tr>
<tr>
<td>11.3</td>
<td>Sensitization May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.</td>
</tr>
<tr>
<td>11.4</td>
<td>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) of Embrace resins may cause eye and respiratory irritation.</td>
</tr>
<tr>
<td>11.5</td>
<td>Carcinogenicity, Mutagenicity, Reproductive Toxicity None known</td>
</tr>
<tr>
<td>11.6</td>
<td>Empirical data Not available</td>
</tr>
</tbody>
</table>
11.7 Clinical experience  
Embrace products have been on the market in the US and internationally for more than 10 years. There have been 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 III medical devices

16.0 Other information

16.1 List of relevant R phrases  
R 36 / 3 7/ 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 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 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.