


Trade Name: **EMBRACE™ Product Line**

1.0 Commercial Product Name and Supplier	
1.1	<p><i>Commercial product name</i></p> <p>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</p>
	<p><i>Codes</i></p> <p>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,</p>
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	<p>Manufacturer</p> <p>Pulpdent Corporation 80 Oakland Street Watertown, MA 02472 USA</p>
	<p>Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p>
1.4	Emergency Telephone Number 1-800-535-5053 (24 Hour / USA)
1.5	<p>Authorized European Representative</p> <p>Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p>

2.0 Hazards Identification																
2.1	Classification															
2.1.1	<p>Classification according to Regulation (EC) No 1272/2008 [CLP]</p> <table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></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>	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317
<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>														
Eye irritation	2	H319														
STOT SE	3	H335														
Skin irritation	2	H315														
Skin sensitization	1	H317														
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	<p>GHS Label Elements</p> <p>Hazard Pictograms</p>  <p>Signal Word: WARNING</p> <p>Restricted to use by dental professional only.</p> <p>Hazard Statements</p> <p>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.</p> <p>Precautionary Statements</p> <p>P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P305+P351: If in eyes, rinse cautiously with water for several minutes.</p>															

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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

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
Proprietary	Uncured acrylate ester monomers	55-60%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2 STOT SE 3 Skin irritation, 2 Skin sensitization, 1
112945-52-5	Silica, amorphous	5 %	Irritant; Xi, R 36/37/38	Eye irritation, 2 STOT SE 3 Skin irritation, 2
7681-49-4	Sodium fluoride	<1%	Harmful (Xn); R22-36/38	Acute toxicity, 4 Skin irritation, 2 Eye irritation, 2

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.

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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

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

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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.

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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 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 Product Line is to be sold to and used by dental professionals only.

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| 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)
Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).
Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency |
| 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. |
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