

SAFETY DATA SHEETS

This SDS packet was issued with item:

075897244


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

075897236

Trade Name: **EMBRACE™ Product Line**

1.0 Commercial Product Name and Supplier	
1.1	<p><i>Commercial product name</i> Code</p> <p>Embrace™ WetBond™ Class V EMVA2, EMVA3.5, EMVB2, EMVD2</p> <p>Embrace™ WetBond™ First Coat EMFC</p> <p>Embrace™ Esthetic Opaquer EMOK, EMO1, EMO2, EMO3, EMO4, EMO5</p> <p>Embrace™ WetBond™ Pit & Fissure Sealant EMS, EMS3, EMSB, EMSW, EMS3W, EMSWB</p> <p>Embrace™ WetBond™ Pit & Fissure Sealant Low Fill EMSWLF, EMSWLFB</p> <p>Embrace™ WetBond™ Seal-n-Shine™ EMSNS, EMSNY</p> <p>Embrace™ WetBond™ Resin Cement 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	Manufacturer, Importer
1.3.1	<p>Manufacturer</p> <p>Pulpdent Corporation Telephone: 1 617 926-6666</p> <p>80 Oakland Street Fax: 1 617 926-6262</p> <p>Watertown, MA 02472 USA 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>International Business Solutions Ltd. Tel: 07989 407479</p> <p>54 Mayfield Ridge Fax: 01256 350330</p> <p>Hatch Warren, Basingstoke, RG22 4RS UK Email: s.williams5@btconnect.co.uk</p>

2.0 Hazards Identification																					
2.1	Classification																				
2.1.1	<table border="1"> <thead> <tr> <th>Classification according to Regulation (EC) No 1272/2008 [CLP]</th> <th>Hazard Class</th> <th>Hazard Category</th> <th>Hazard Statement</th> </tr> </thead> <tbody> <tr> <td></td> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td></td> <td>STOT SE</td> <td>3</td> <td>H335</td> </tr> <tr> <td></td> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> <tr> <td></td> <td>Skin sensitization</td> <td>1</td> <td>H317</td> </tr> </tbody> </table>	Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement		Eye irritation	2	H319		STOT SE	3	H335		Skin irritation	2	H315		Skin sensitization	1	H317
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2.1.2	<p>Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)</p> <p>Irritant; Xi; R 36/37/38 - 43</p>																				

2.2	GHS Label Elements
	Hazard Pictograms
	
	Signal Word: WARNING

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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			
CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
Proprietary	Uncured acrylate ester monomers	55-60%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
112945-52-5	Silica, amorphous	5 %	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315

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

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4.6	Precautions for first responders	by mouth to an unconscious person. 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 fire fighting personnel. 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 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

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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														
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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														

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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 in the quantity present in this product and 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. Prolonged exposure to large amounts (more than in this product) of Embrace resins may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available

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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.
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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) 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.
