

Trade Name: **EMBRACE™ Product Line**

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name	Codes	
	Embrace™ WetBond™ Class V	EMVA2, EMVA3.5, EMVB2, EMVD2	
	Embrace™ WetBond™ First Coat	EMFC	
	Embrace™ Esthetic Opaquer	EMOK, EMO1, EMO2, EMO3, EMO4, EMO5	
	Embrace™ WetBond™ Pit & Fissure Sealant	EMS, EMS3, EMSB, EMSW, EMS3W, EMSWB	
	Embrace™ WetBond™ Pit & Fissure Sealant Low Fill	EMSWLF, EMSWLFb	
	Embrace™ WetBond™ Seal-n-Shine™	EMSNS, EMSNY	
	Embrace™ WetBond™ Resin Cement	EMCA, EMCAR, EMCAR2, EMCM, EMCMR, EMCMR2,	
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	Telephone: 1 617 926-6666	
	Pulpdent Corporation	Fax: 1 617 926-6262	
	80 Oakland Street	Email: Pulpdent@pulpdent.com	
	Watertown, MA 02472 USA		
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]	<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	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.		

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

13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
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14.0 Transport Information

14.1	Restrictions	None. Not regulated.
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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.
