

SAFETY DATA SHEETS


This SDS packet was issued with item:

075897202

N/A

Trade Name: **EMBRACE™ Product Line**

| 1.0 Commercial Product Name and Supplier | |
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| 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

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|-----|----------------------------------|--|
| 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

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|-----|------------------------------------|---|
| 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 | <table border="0"> <thead> <tr> <th><u>Embrace Product</u></th> <th><u>Description</u></th> </tr> </thead> <tbody> <tr> <td><i>First Coat, Seal-n-Shine</i></td> <td>Thin, clear liquid</td> </tr> <tr> <td><i>Esthetic Opaquer</i></td> <td>Opaque, thick paste: Bleach White, Off-White, Light Yellow, Pink, Dark Yellow</td> </tr> <tr> <td><i>Pit and Fissure Sealant</i></td> <td>Natural tooth shade or off-white thin paste.</td> </tr> <tr> <td><i>Pit and Fissure Sealant, Low Fill</i></td> <td>Off-white thin paste</td> </tr> <tr> <td><i>Class V</i></td> <td>Tooth-colored paste.</td> </tr> <tr> <td><i>Resin Cement:</i></td> <td>Two thin pastes: one white, one yellow.</td> </tr> </tbody> </table> | <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. |
| <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

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| 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

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|------|---|---|
| 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. |
