


Safety Data SheetTrade Name: **EMBRACE VARNISH**

| 1.0 Commercial Product Name and Supplier | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|---|---------------------|------------------------|-------------------------|------------------|---|------|----------------|---|------|-----------------|---|------|--------------------|---|------|----------------|---|------|---------------------------|---|------|---------|---|------|--|
| 1.1 | Commercial product name / designation | EMBRACE VARNISH – 5% Sodium Fluoride with CXP™ | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.2 | Application / Use | Dental material | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.2.2 | SIC | 851 Human health activity | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.2.3 | Use Category | 55 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1.3 | Manufacturer | Pulpdent Corporation 80 Oakland Street Watertown, MA 02472 USA Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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] | <table><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>Flammable liquid</td><td>3</td><td>H226</td></tr><tr><td>Acute toxicity</td><td>4</td><td>H302</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><tr><td>Eye irritation</td><td>2</td><td>H319</td></tr><tr><td>Respiratory sensitization</td><td>1</td><td>H334</td></tr><tr><td>STOT SE</td><td>3</td><td>H335</td></tr></tbody></table> | <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | Flammable liquid | 3 | H226 | Acute toxicity | 4 | H302 | Skin irritation | 2 | H315 | Skin sensitization | 1 | H317 | Eye irritation | 2 | H319 | Respiratory sensitization | 1 | H334 | STOT SE | 3 | H335 | |
| <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | | | | | | | | | | | | | | | | | | | | | | | | | |
| Flammable liquid | 3 | H226 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Acute toxicity | 4 | H302 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin irritation | 2 | H315 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Skin sensitization | 1 | H317 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Eye irritation | 2 | H319 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Respiratory sensitization | 1 | H334 | | | | | | | | | | | | | | | | | | | | | | | | | |
| STOT SE | 3 | H335 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1.2 | Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) | Harmful (Xn) R22; Flammable (F) R11 Irritant (Xi) R36/37/38-42/43 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.2 | GHS Label Elements | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Hazard Pictograms | | | | | | | | | | | | | | | | | | | | | | | | | | |
| |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Signal Word: WARNING | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Restricted to use by dental professional only | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Hazard Statements: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H226: Flammable liquid and vapor. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H302: Harmful if swallowed | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H315: Causes skin irritation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H317: May cause an allergic skin reaction | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H319: Causes serious eye irritation | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H334: May cause allergy or asthma symptoms | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, may cause respiratory irritation. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Precautionary Statements: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking. | | | | | | | | | | | | | | | | | | | | | | | | | | |

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P280: Wear protective gloves/clothing and eye protection.

P302+P350: If on skin, gently wash with plenty of soap and water.

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P333+P313: If skin irritation or rash occurs, get medical advice/attention.

P342+P315: If experiencing respiratory symptoms, get immediate medical advice/attention.

P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.

3.0 Composition

3.1 Chemical characterization of the preparation Resin-based dental varnish

3.2 Hazardous Ingredients

| CAS Number | Name of the Ingredient | Concentration | Classification per 67/548/EEC | Classification per Regulation (EC) No.1272/2008 (CLP). |
|-------------|------------------------|---------------|--|--|
| Mixture | Hydrogenated rosin | < 35% | Irritant (Xi), R36/37/38 R42/43 | Skin irritation, 2, H315 Skin sensitizer, 1, H317 Eye irritation, 2, H319 Respiratory sensitizer, 1, H334 STOT SE, 3, H335 |
| 64-17-5 | Ethanol, 190 proof | < 20% | Flammable (F); Irritant (Xi). R11- 36/37/38-66 | Flammable liquid, 2, H226 Skin irritation, 2, H315 Eye irritation, 2, H319 STOT SE, 3, H335 |
| 7681-49-4 | Sodium fluoride | 5% | Harmful (Xn); R22-36/38 | Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319 |
| 112945-52-5 | Amorphous fumed silica | < 3% | Irritant (Xi) R36/37/38 | Skin irritation, 2, H315 Eye irritation, 2, H319 STOT SE 3, H335 |

4.0 First Aid Measures4.1 General Information **Embrace Varnish, applied to the patient's teeth in the recommended dosage, is a minimal health hazard.****NOTE:** Although the rosin is hydrogenated and highly refined, it may cause an allergic reaction in susceptible individuals.

Sodium fluoride overdose is not an issue with this product. A typical application of varnish would deliver less than 0.01 g of sodium fluoride to an adult's dentition, less than 0.005 g to a child's, well below the level that would cause adverse symptoms.

Ingestion or absorption of large amounts of ethanol (much greater than in this product) may cause central nervous system effects. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

- 4.2 Inhalation Move person to fresh air. Seek immediate medical attention for difficulty breathing, allergic reaction or any other respiratory effects.
- 4.3 Skin Contact Wash skin thoroughly with soap and water. Seek immediate medical attention for allergic reaction.
- 4.4 Eye Contact Keep eyelids apart and flush with running water for 15+ minutes. Remove contact lenses after several minutes. If effects occur, consult an ophthalmologist.

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| 4.5 | Ingestion | For ingestion of large amounts (greater than in this product) contact Poison Control Center or physician. Induce vomiting only on medical advice. Never give anything by mouth to an unconscious person |
| 4.6 | Precautions for first responders | Wear safety glasses and gloves. |
| 4.7 | Information for physicians | |
| | Symptoms | Allergic reaction: Skin rash, asthma symptoms, and anaphylaxis. Eye contact: Irritation, redness. Skin contact: Irritation, redness, rash. Inhalation: Respiratory irritation. Ingestion: No effects anticipated with the small amount of varnish in typical application. |
| | Hazards | Flammable liquid and vapor. May cause irritation to skin, eyes or respiratory tract on contact. May be the cause of an allergic reaction. |
| | Treatment | Same as above under First Aid. |

5.0 Fire Fighting Measures

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|-----|--|---|
| 5.1 | Suitable extinguishing media | Use dry chemical, alcohol foam, or carbon dioxide. |
| 5.2 | Extinguishing media to avoid | Water may be ineffective, but will keep fire-exposed containers cool. |
| 5.3 | Special exposure hazards in a fire | Carbon monoxide, carbon dioxide from incomplete combustion |
| 5.4 | Special protective equipment for fire-fighters | Self-contained breathing apparatus. |

6.0 Accidental Release Measures

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|-----|---------------------------|--|
| 6.1 | Personal precautions. | Wear safety glasses, gloves and lab coat. |
| 6.2 | Environmental precautions | Follow all government regulations. |
| 6.3 | Method for clean up | Absorb or wipe up spill with paper towels or disposable cloths. Collect for disposal in a covered container. Wash area of spill with soap and water. |

7.0 Handling and Storage

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| 7.1 | Handling | For intraoral use by dental professionals. Follow good hygiene practices. Unit dose pouches are to be used on one patient and disposed. Multi-dose tubes should be encased in fresh plastic barrier for each patient. Cap tube immediately after use. |
| 7.2 | Storage | Keep tube capped. Store tubes and pouches at cool room temperature (<25°C). 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 material: fluoride varnish to be applied to tooth surfaces. |

8.0 Exposure Controls / Personal Protection

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|---------|--------------------------------|---|
| 8.1 | Exposure limit values | PEL: Not established. TLV: Not established. |
| 8.2 | Exposure controls | |
| 8.2.1 | Occupational exposure controls | No special equipment |
| 8.2.1.1 | Respiratory protection | None required |
| 8.2.1.2 | Hand protection | Usual surgical gloves under normal conditions of use. |

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| 8.2.1.3 | Eye protection | Usual safety glasses under normal conditions of use |
| 8.2.1.4 | Skin protection | Good personal hygiene, lab coat and gloves. |
| 8.2.1.5 | Other controls | Emergency eye wash fountain should be available. Wash hands after use. |
| 8.2.2 | Environmental exposure controls | Follow all government regulations. |

9.0 Physical and Chemical Properties

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|--------|--|---|
| 9.1 | Characteristics | Soft, white gel that brushes out to a transparent layer |
| 9.1.1 | Appearance /Color / Physical state | None, unless flavored |
| 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 determined |
| 9.2.5 | Explosive properties | Not applicable |
| 9.2.6 | Oxidizing properties | Not applicable |
| 9.2.7 | Vapor pressure | Not determined |
| 9.2.8 | Specific gravity | 1.050 |
| 9.2.9 | Solubility in water | Not determined |
| 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 greater than 25°C/77°F, any ignition source. |
| 10.2 | Materials to avoid | Acetyl chloride and a wide range of oxidizing agents. |
| 10.3 | Hazardous decomposition products | Carbon monoxide, carbon dioxide, nitrogen oxides from combustion |
| 10.4 | Further information | Stable material |

11.0 Toxicological information

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| 11.1 | Acute toxicity | <i>Sodium fluoride</i> : Oral rat LD ₅₀ : 0.18 g/kg <i>Ethanol</i> : Oral LD ₅₀ in young rats: 10.6 g/kg; Oral LD ₅₀ in old rats: 7.06 g/kg. |
| 11.2 | Irritation and corrosiveness | May be irritating to eyes or skin on contact. Ethanol may cause irritation of respiratory tract if inhaled. |
| 11.3 | Sensitization | Rosin may cause an allergic reaction in susceptible individuals. |
| 11.4 | Sub-acute, sub-chronic and prolonged toxicity | Chronic overdose of sodium fluoride may cause mottling of tooth enamel. |

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| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | <i>Ethanol</i> : Not a carcinogen under normal conditions of use. Prolonged ingestion of large quantities of ethanol may be carcinogenic or a cause of Fetal Alcohol Syndrome. IARC has reported a relationship between habitual drinking of significant quantities of alcoholic beverages and cancer of oral cavity, pharynx, esophagus, liver. |
| 11.6 | Empirical data | Not available |
| 11.7 | Clinical experience | Fluoride varnishes, similar to Embrace Varnish, have been used safely and effectively by dental professionals for more than 15 years. |

12.0 Ecological Information

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| 12.1 | Ecotoxicity | Follow good work practices and government regulations. Avoid release into environment. |
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13.0 Disposal Considerations

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|------|-------------|---|
| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
|------|-------------|---|

14.0 Transport Information

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|------|----------------|---------------|
| 14.1 | UN Number | 1170 |
| | Technical name | Ethyl alcohol |
| | Packing group | II |
| | IATA class | 3 |

15.0 Regulatory Information

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|------|---------------|---|
| 15.1 | EU | Class IIa medical device under MDD 93/42/EEC. |
| 15.2 | US FDA | Class II medical device |
| 15.3 | Health Canada | Class III medical device |

16.0 Other information

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|------|----------------------------|--|
| 16.1 | List of relevant R phrases | R11: Highly flammable R22: Harmful if swallowed. R36/37/38: Irritating to eyes, respiratory system and skin. R 42/43: May cause sensitization by skin contact or inhalation. |
| 16.2 | Hazard Statements | H226: Flammable liquid and vapor. Category 3. H302: Harmful if swallowed, Category 4. H315: Causes skin irritation. Category 2. H317: May cause an allergic skin reaction. Category 1 H319: Causes serious eye irritation. Category 2. H334: May cause allergy or asthma symptoms. Category 1 H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. |

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|------|---|---|
| 16.3 | Precautionary Statements | <p>P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.</p> <p>P280: Wear protective gloves/clothing and eye protection.</p> <p>P302+P350: If on skin, gently wash with plenty of soap and water.</p> <p>P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P333+P313: If skin irritation or rash occurs, get medical advice/attention.</p> <p>P342+P315: If experiencing respiratory symptoms, get immediate medical advice/attention.</p> <p>P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.</p> |
| 16.3 | Restrictions on use | Pulpdent products are to be sold to and used by dental professionals only. |
| 16.4 | 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. |
| 16.5 | Sources of key data | <p>National Institute for Occupational Safety (NIOSH)</p> <p>US Occupational Safety and Health Administration (OSHA)</p> <p>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).</p> <p>Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency</p> |
| 16.6 | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |
