


Safety Data SheetTrade Name: **EMBRACE VARNISH**

1.0 Commercial Product Name and Supplier																											
1.1	Commercial product name / designation	<i>EMBRACE VARNISH – 5% Sodium Fluoride with CXP™</i>																									
1.2	Application / Use	Dental material																									
1.2.2	SIC	851 Human health activity																									
1.2.3	Use Category	55																									
1.3	Manufacturer	<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	Authorized European Representative	<p>Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta</p>																									
2.0 Hazards Identification																											
2.1	Classification																										
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<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>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	
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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.																										
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Safety Data SheetTrade Name: **EMBRACE VARNISH****Precautionary Statements:**

P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.

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.

Safety Data SheetTrade Name: **EMBRACE VARNISH**

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

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

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

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

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.

Safety Data SheetTrade Name: **EMBRACE VARNISH**

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

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

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

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.

Safety Data SheetTrade Name: **EMBRACE VARNISH**

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

12.1	Ecotoxicity	Follow good work practices and government regulations. Avoid release into environment.
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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	UN Number	1170
	Technical name	Ethyl alcohol
	Packing group	II
	IATA class	3

15.0 Regulatory Information

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

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.

Safety Data SheetTrade Name: **EMBRACE VARNISH**

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	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
16.6	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.
