

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>International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK</p> <p>Tel: 07989 407479 / Fax: 01256 350330 Email: s.williams5@btconnect.co.uk</p>	
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>
		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		

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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.

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.1278/2008 (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 Measures

4.1 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. In the entire pouch, there is 0.02 g of sodium fluoride. 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 the 0.08 ml in the unit dose pouch) may cause central nervous system effects.

Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

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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.
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 each unit dose pouch.
	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. Water may be ineffective, but should be used to keep fire-exposed containers cool.
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 suitable material (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	Medical device for intraoral use only by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. 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.
7.2	Storage	Keep container closed. Store product in original container 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.

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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.
8.2.1.3	Eye protection	Usual safety glasses under normal conditions of use
8.2.1.4	Skin protection	No special requirements other than 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	Appearance / Color	Soft, white gel that brushes out to a transparent layer
9.1.1	Odor	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, sparks, open flame, 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 burning.
10.4	Further information	Stable material

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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.
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 on the market and used successfully by dental professionals for more than 15 years with no serious safety or effectiveness problems.
12.0 Ecological Information		
12.1	Ecotoxicity	Follow good work practices and government regulations. Avoid release into environment.
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	UN Number	1170
	Technical name	Ethyl alcohol
	Packing group	II
	IATA class	3
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	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.

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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.
16.3	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.
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.
