



Trade Name: **Ethanol-based Materials: DRY-RITE / SILANE BOND ENHANCER**

1.0 Commercial Product Name and Supplier				
1.1	Commercial product name / designation	Dry-Rite Drying Agent Silane Bond Enhancer		
1.2	Application / Use	Dental material for use by dental professionals.		
1.2.2	SIC	851 Human health activity		
1.2.3	Use Category	55		
1.3	Manufacturer, Importer	Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com		
1.3.1	Manufacturer			
Pulpdent Corporation 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA				
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)		
1.5	Authorized European Representative	Tel: 07989 407479 Fax: 01256 350330 Email: s.williams5@btconnect.co.uk		
International Business Solutions Ltd.				
54 Mayfield Ridge, Hatch Warren				
Basingstoke, RG22 4RS UK				
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	2	H225
		Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315; EUH066
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Flammable (F) R11 Irritant (Xi) R36 / 37 / 38 – 66		
2.2 Label Elements				
Labeling according to Regulation (EC) No 1272/2008 [CLP]				
Hazard Pictograms				
 				
Signal Word: DANGER				
Restricted to use by dental professional only				
Hazard Statements:				
H225: Highly flammable liquid and vapor. Category 2.				
H319: Causes serious eye irritation. Category 2.				
H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation.				

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H315: Causes skin irritation. Category 2.

EUH066: Repeated exposure may cause skin dryness or cracking.

Precautionary Statements:

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

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P261: Avoid breathing fumes.

P280: Wear protective gloves/ clothing and eye protection.

P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.

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: Denatured ethyl alcohol preparation.

3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
64-17-5	Ethyl alcohol	92%	Flammable (F); Irritant (Xi). R11- 36/ 37/38-66	Flammable liquid, Category 2 Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.
67-64-1	Acetone (denaturant)	7%	Flammable (F); Irritant (Xi). R11- 36/ 37/38-66	Flammable liquid, Category 2 Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2.

4.0 First Aid Measures

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|-----|----------------------------------|--|
| 4.1 | General Information | May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. |
| 4.2 | Eye Contact | Keep eyelids apart, flush with running water for 15+ minutes. Get medical attention. |
| 4.3 | Skin Contact | Remove contaminated clothing. Immediately wash with soap, running water. Use hand cream. Get medical attention if irritation persists. |
| 4.4 | Ingestion | Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. Never give anything by mouth to an unconscious person. |
| 4.5 | Inhalation | Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention. |
| 4.6 | Precautions for first responders | Ventilate the area. Wear safety glasses and gloves. |
| 4.7 | Information for physicians | |

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Symptoms	Contact with material may cause irritation or redness in eyes or on skin. Inhalation may cause irritation of respiratory tract.	
Hazards	Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Persons with chronic respiratory or skin disease are at increased risk with prolonged and/or repeated contact.	
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 chemical splash goggles and gloves.
6.2	Environmental precautions	Avoid releasing large quantities into environment.
6.3	Method for clean up	For small quantities: Ventilate area. Wear safety glasses, lab coat, gloves. Wipe up with absorbent material (paper or cloth towels). Rinse area of spill with water. Place all material in closed container away from heat, sparks, sun and oxidizers.
7.0	Handling and Storage	
7.1	Handling	For use by dental professionals only. Remove applicator tip and recap immediately after use. Keep material tightly capped in original container. Do not use in presence of ignition sources. Take same precautions when container is emptied, as residual product is hazardous.
7.2	Storage	Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature in a well-ventilated area. Avoid extreme temperatures (>27°C/80°F, <5°C/40°F), sparks, direct sunlight, oxidizing agents. Vapor may form flammable mixtures with air.
7.3	Specific uses	<i>Dry-Rite</i> : Dental drying agent; <i>Silane</i> : Material used to enhance bonding of porcelain to resin composites and luting agents.
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	Ethanol: 1000 ppm; Acetone: 750 ppm
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment or ventilation required under normal conditions of use in dental practice. For large quantities/prolonged exposure, use enclosure, local ventilation, dilution to reduce concentration below TLV.
8.2.1.1	Respiratory protection	No special requirements under normal conditions of use. Good general ventilation is sufficient to control any airborne vapors.

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8.2.1.2	Hand protection	No special requirements other than surgical gloves.
8.2.1.3	Eye protection	No special requirements other than safety glasses.
8.2.1.4	Skin protection	No special requirements other than good hygiene and safety practices.
8.2.1.5	Other controls	Emergency eye wash fountain should be close by and maintained. Wash hands after use. Do not eat, drink or smoke.
8.2.2	Environmental exposure controls	Follow all government regulations.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	
9.1.1	Color	Dry-Rite: Pink liquid Silane: Clear liquid
9.1.2	Odor	Characteristic, sweet, ethanol odor
9.2	Important health, safety and environmental information	
9.2.1	pH	Not applicable
9.2.2	Boiling point	Boiling Point: 173°F / 78.3°C
9.2.3	Flash point	43°F / 6°C (Tag closed cup)
9.2.4	Ignition temperature	423°C
9.2.5	Explosive properties	LEL: 3.3; UEL: 19
9.2.6	Odor threshold	159 ppm
9.2.7	Vapor pressure	44.6 mm Hg / 59 mbar / Id: E
9.2.8	Specific gravity	0.795
9.2.9	Solubility in water	Dry-Rite: Complete Silane: Slight
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	1.59
9.2.13	Evaporation rate	Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	Heat, 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 from incomplete combustion.
10.4	Further information	Stable if stored and used as directed.

11.0 Toxicological information

11.1	Acute toxicity	Minimal health hazard under normal conditions of use. Ethanol: LD ₅₀ in young rats: 10.6 g/kg orally; LD ₅₀ in old rats: 7.06 g/kg orally. Acetone: LD ₅₀ in rats : 10.7 ml/kg orally
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11.2	Irritation and corrosiveness	May cause irritation/redness of eyes or skin on contact. May cause irritation of respiratory tract if inhaled.
11.3	Sensitization	Not applicable.
11.4	Sub-acute, sub-chronic and prolonged toxicity	No chronic health hazard under normal conditions of use.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	Not a carcinogen under normal conditions of use. Large quantities of ethanol, ingested over time, 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	None available
11.7	Clinical experience	<i>Dry-Rite, Silane</i> and similar products have been used in dentistry for decades with no reported 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
14.2	Technical name	Ethyl alcohol
14.3	Packing group	II
14.4	IATA class	3
15.0 Regulatory Information		
15.1	EU	Dry-Rite (Class I) and Silane (Class IIA) are medical devices under MDD 93/42/EEC.
15.2	US FDA	Dry-Rite and Silane are Class II medical devices
15.3	Health Canada	Dry-Rite (Class I) and Silane (Class III) medical devices
16.0 Other information		
16.1	List of relevant R phrases	R11: Highly flammable R36/37/38: Irritating to eyes, respiratory system and skin. R66: Repeated exposure may cause skin dryness or cracking.
16.2	Hazard Statements	H225: Highly flammable liquid and vapor. Category 2. H319: Causes serious eye irritation. Category 2. H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. H315: Causes skin irritation. Category 2. EUH066: Repeated exposure may cause skin dryness or cracking.

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16.3	Precautionary Statements	<p>P210: Keep away from heat, sparks, open flame, hot surfaces. No smoking.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P261: Avoid breathing fumes.</p> <p>P280: Wear protective gloves/ clothing and eye protection.</p> <p>P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.</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>P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water.</p> <p>P370+P378: In case of fire, use dry chemical, alcohol foam, or carbon dioxide for extinction.</p>
16.4	Restrictions on use	<p>Pulpdent dental materials, such as Dry-Rite and Silane, are to be sold to and used by dental professionals only.</p>
16.5	Further information	<p>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.</p>
16.6	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>
16.7	Information which has been added, deleted or revised.	<p>This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, 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.</p>
