

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Trade Name: **Silane Bond Enhancer**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	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	
1.3.1	Manufacturer	Pulpdent Corporation 80 Oakland Street P.O. Box 780 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	International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcqc@globalnet.co.uk
2.0 Hazards Identification		
2.1	Classification	Class 3, Flammable liquid
2.2	Adverse human health effects	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.
3.0 Composition		
3.1	Chemical characterization of the preparation:	Mixture of silane and denatured ethanol.

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Trade Name: **Silane Bond Enhancer****3.2 Hazardous ingredients**

CAS Number	EC Number	Name of the Ingredient	Concentration	Warning symbol, R phrases
64-17-5	200-578-6	Ethyl alcohol	92%	F R11
67-64-1	200-662-2	Acetone (denaturant)	7%	F, Xi. R11 - 36/ 37/38 - 66-67.

4.0 First Aid Measures

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 and flush with running water for 15+ minutes. Get medical attention.
4.3	Skin Contact	Remove any contaminated clothing. Immediately wash skin well with soap and 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	
	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.

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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 should be used to 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	A self-contained breathing apparatus should be worn by fire fighting personnel.
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 (as in this product): Ventilate area. Wear safety glasses, lab coat and gloves. Wipe up with absorbent material, such as 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. Protect container against physical damage. Do not use in the presence of sources of ignition. 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 heat, sparks, direct sunlight, and oxidizing agents. Vapor may form flammable mixtures with air.
7.3 Specific uses	Silane Bond Enhancer is used to increase the bond strength of composites and resin cements to porcelain surfaces
8.0 Exposure Controls / Personal Protection	

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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 of this product in the quantity provided. For large quantities and prolonged exposure, methods such as enclosure, local ventilation and dilution are recommended to reduce concentration below TLV.
8.2.1.1	Respiratory protection	No special requirements under normal conditions of use in the quantity provided in this product. Good general ventilation is sufficient to control any airborne vapors.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will limit contact with this material.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by dental staff.
8.2.1.4	Skin protection	No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Wash hands after use. Do not eat, drink or smoke while using this product.
8.2.2	Environmental exposure controls	Do not release large quantities into the environment. Follow all government regulations.
9.0	Physical and Chemical Properties	
9.1	Appearance / Color	
9.1.1	Color	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

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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	Complete
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 in normal use and in the quantities present in this product. 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
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 prolonged time, may be carcinogenic or a cause of Fetal Alcohol Syndrome. The IARC has reported a relationship between repeated drinking of significant quantities of alcoholic beverages and cancer of the oral cavity, pharynx, esophagus and liver.

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11.6	Empirical data	None available
11.7	Clinical experience	A typical application of Silane Bond Enhancer is a drop or two applied to an etched and dried porcelain surface and allowed to evaporate. <i>Silane</i> and other alcohol-based materials have been used in dentistry for decades with no reported problems.

12.0 Ecological Information

12.1	Ecotoxicity	Use according to good working practices. Avoid release into environment. Follow all government regulations.
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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
14.2	Technical name	Ethyl alcohol
14.3	Packing group	II
14.4	IATA class	3

15.0 Regulatory Information

15.1	EU Regulations	<i>Silane Bond Enhancer</i> is a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC.
15.2	Information on the warning label	Warning! Flammable.
15.2.1	Hazard symbol	F, Xi
15.2.2	Hazardous ingredients	Ethyl alcohol; Acetone (denaturant)
15.2.3	Risk phrases	R11: Highly flammable R36/ 37/38: Irritating to eyes, respiratory system and skin. R66: Repeated exposure may cause skin dryness or cracking. R67: Vapors might cause drowsiness or dizziness.
15.2.4	Safety phrases	S7/9: Keep container tightly closed and in a well ventilated area. S16: Keep away from sources of ignition.

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S24/25: Avoid contact with skin and eyes.

S26: In case of contact with eyes, rinse immediately with running water and seek medical advice.

S28: After contact with skin, wash immediately with soap and running water.

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. R67: Vapors might cause drowsiness or dizziness.
16.2	Training advice	Pulpdent dental materials are to be used only by dental professionals who have been trained in their use.
16.3	Restrictions on use	Pulpdent dental materials 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) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of Commission Regulation (EC) No. 1907/2006 (REACH).