PULPDENT

Silane
Bond Enhancer

4 x 1.2ml Silane

PULPDENT®

Silane
Bond Enhancer

Rx only

PULPDENT Corporation • 80 Oakland Street • Watertown, MA 02472 • U.S.A.
www.pulpdent.com • pulpdent@pulpdent.com

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	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 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.
16.3	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.
16.4	Restrictions on use	Pulpdent dental materials are to be sold to and used by dental professionals only.
16.5	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.
16.6	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
16.7	Information which has been added, deleted or revised.	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.

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XK-SIL-IN-24
REV: 01/2020

PULPDENT®

Silane Bond Enhancer

CE 0459

PULPDENT SILANE is a single-component material which is used to promote increased bond strength between organic resins and porcelain. To achieve desired results, the etched porcelain surface must be completely dry and free of residual moisture before applying silane.

CONTROLLED DISPENSING

Syringe dispensing with Pulpdent's unique red dropper tips eliminates waste and provides controlled dispensing of silane.
Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm

DIRECTIONS FOR USE

1. Carefully follow instructions for Pulpdent Porcelain Etch Gel, and etch porcelain surface to be treated. Rinse and dry.
2. Apply Pulpdent Dry-Rite™ drying agent to etched surface to assure that it is completely dry. Residual moisture will adversely effect bonding.
3. Place 22-gauge red dropper tip on silane syringe and apply Pulpdent Silane Bond Enhancer to treated porcelain surface. Allow to dry. A gentle flow of uncontaminated, oil-free and moisture-free air may be applied to accelerate drying. Cap syringe immediately after use. To check air line for contamination, blow air onto the surface of dental mirror. If streaks of water or droplets of oil appear, do not use the air line for this procedure.
4. Maintain a clean, dry field. Apply unfilled resin bonding agent and proceed with your preferred restorative composite or resin cement.

Français
SILANE

Le SILANE "Pulpdent" est un produit mono-composant utilisé pour renforcer le collage entre les composites ou les résines et la céramique lors des réparations de fractures, notamment.
Pour obtenir un bon résultat, la céramique mordançée doit être sèche et exempte d'humidité avant l'application du SILANE.
La présentation en seringue permet de contrôler le débit et évite donc de gâcher du produit.

Mode d'emploi

1. Suivre scrupuleusement le mode d'emploi du Porcelain Etch Gel et mordançer la surface à coller. Rincer et sécher.
2. Appliquer DRY RITE, agent déssicant sur la surface mordançée pour l'assécher parfaitement.
3. Placer un embout sur la seringue de SILANE et déposer le produit sur la surface de porcelaine mordançée et sèche. Laisser le produit sécher. Un léger jet d'air non contaminé permet d'accélérer le séchage. Recapuchonner la seringue immédiatement après usage.
4. A l'aide de cotons salivaires ou d'une digue, maintenir un champ opératoire sec et propre. Appliquer une résine non chargée et continuer la procédure avec votre composite habituel.

Deutsch
SILANE

Haftverstärker
Pulpdent Silane ist ein Einkomponenten Material zur Haftverstärkung zwischen Kompositmaterialien und Porzellan.
Um die gewünschten Haftwerte zu erhalten, muss die geätzte Porzellanoberfläche vor der Applkation von Silane absolut trocken und sauber sein.

Kontrollierte Applikation

Die Benützung der Pulpdent red dropper tips minimiert den Verbrauch und fördert die kontrollierte Applikation von Silane.

Gebrauchsanweisung

1. Befolgen Sie genau die Instruktionen für Pulpdent Porcelain Etch Gel, und ätzen Sie die entsprechende Porzellanoberfläche. Spülen und trocknen.
2. Applizieren Sie Dry-Rite Trocknungsmittel auf die geätzte Oberfläche, um eine absolut trockene Oberfläche zu erreichen. Verbleibende Feuchtigkeit führt zu schlechteren Haftwerten.
3. Befestigen Sie eine red dropper tip auf der Silane Spritze, applizieren Sie Silane auf die geätzte Porzellanoberfläche, und lassen Sie es eintrocknen. Ein leichtes Blasen mit öl-und feuchtigkeitsfreier Luft beschleunigt das Eintrocknen. Verschliessen Sie die Spritze sofort nach Gebrauch. Um die Luft auf mögliche Kontamination zu prüfen, blasen Sie mit der Luftspritze auf einen Spiegel. Wenn Wasser- oder Oeltropfen auf der Spiegeloberfläche erscheinen, benützen Sie eine andere Luftzufuhr.
4. Achten Sie weiterhin auf eine saubere, trockene Oberfläche. Applizieren Sie Haftvermittler (unfilled bonding resin) auf die Porzellanoberfläche, und fahren Sie mit der Zementierung fort.

Italiano
SILANE

Rinforzatore di aderenza
Pulpdent Silane è un materiale basato su una sola componente che rinforza l'adesione tra compositi e porcellana. Per ottenere ottimi risultati adesivi, le superfici della porcellana corrosa devono essere perfettamente asciutte e pulite prima di applicare Silane.

Applicazione controllata:

L'uso di Pulpdent red dropper tips minimizza il consumo e favorisce l'applicazione controllata.

1. Seguire attentamente le avvertenze per l'uso di Pulpdent Porcelain Etch Gel; mordenzare la superficie da trattare, poi sciacquarla e asciugarla.
2. Applicare l'agente essiccante Dry-Rite sulla superficie mordenzata per assicurare che sia assolutamente asciutta. Nel caso di residui di umidità si riduce il grado di adesione.
3. Mettere un red dropper tip sulla siringa di Silane ed applicare Silane sulla superficie trattata, dopo lasciarla asciugare. Ricoprire la siringa immediatamente dopo l'uso. Con essicatori ad aria si accelera l'asciugatura, presupposto che l'aria sia secca e non oleosa. Un'eventuale contaminazione dell'aria può essere scoperta facilmente dirigendo il flusso dell'aria su uno specchio. Nel caso di tracce di acqua o di grasso sullo specchio, adoperare un altro essiccatore ad aria.
4. Tenere pulita e asciutta la superficie. Applicare un agente di resina aderente non riempito sulla superficie di porcellana, dopodiché potete procedere con il vostro preferito composto restaurativo o resina di cemento.

Español
SILANO

Aumentador de la adhesión - Agente de Enlace.
Para facilitar el enlace entre el composite y otras resinas orgánicas a la porcelana.
El Silano de Pulpdent es un material monocomponente que se utiliza para promover la adhesión entre resinas orgánicas y porcelana. Para obtener los resultados deseados, la superficie de porcelana a ser grabada deberá estar completamente seca y libre de humedad residual antes de la aplicación del silano.

Instrucciones de Uso

1. Siga cuidadosamente las instrucciones del Pulpdent Porcelain Etch Gel para grabar la superficie de porcelana. Enjuague y seque.
2. Aplique Pulpdent Dry Rite, agente de secado, sobre la superficie para asegurar que el secado haya sido perfecto. Cualquier humedad residual va a afectar negativamente la adhesión.

3. Coloque el pico sobre la jeringa de silano y aplique el agente de Unión de Silano Pulpdent sobre la superficie de porcelana tratada. Déjelo secar por un minuto. Si no se ha secado en ese lapso, sople con aire de la jeringa triple, cuidando que éste no contenga aceite ni humedad. Tape inmediatamente la jeringa. A fin de controlar la calidad del aire, sople con la jeringa sobre la superficie de un espejo dental. Si aparecen marcas o gotitas de agua, no deberá usarse este aire para el procedimiento.
4. Mantenga un campo limpio y seco y aplique cemento dual para el cementado.

Pulpdent Corporation ***Revision Date: January 1, 2020***

Safety Data Sheet

Trade Name: SILANE BONDING AGENT

1.0 Commercial Product Name and Supplier

1.1	Commercial product name\/designation	Silane Bonding Agent
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	Advena Ltd. Tower Business Centre Warwick CV34 6WE UK 2nd Floor, Tower Street Swatar, BKR 4013 Malta

2.0 Hazards Identification

2.1 Classification

2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement
		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 GHS Label Elements

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.
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 Ingredient	Name of the	Concentration 67/548/EEC	Classification per (EC) No.1278/2008 (CLP).	Classification per Regulation
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

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	
	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	Carbon monoxide, carbon dioxide from incomplete combustion hazards in a fire
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	Dental bond enhancer

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.
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	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	Slightly
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 in dental practice
	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 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	0 and similar bond enhancers have been used in dentistry for decades with no reported problems.