



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 | 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: s.williams5@btconnect.com | |
| 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 | 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. | | |

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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 | |
| | 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 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 | 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. For large quantities/prolonged exposure, use enclosure, local ventilation, dilution to reduce concentration below TLV. |
| 8.2.1.1 | Respiratory protection | 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. Wash hands after use. Do not eat, drink or smoke. |
| 8.2.2 | Environmental exposure controls | Follow all government regulations. |

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| 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 | 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 |
| 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. |

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| 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>Silane</i> and similar products have been used in dentistry for decades with no reported problems. |

12.0 Ecological Information

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| 12.1 | Ecotoxicity | Follow good work practices and government regulations. Avoid release into environment. |
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13.0 Disposal Considerations

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| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
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14.0 Transport Information

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| 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

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|------|---------------|---|
| 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 devices |

16.0 Other information

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| 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 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> |
