

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/31/2012

SDS No : 5-001.11

Date Revised : 04/27/2015

Revision No : 11

**Silane****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : SI/10325  
**Product name** : Silane  
**Product description** : Bonding Agent

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses** : Professional Dental Bonding Agent

**1.3. Details of the supplier of the safety data sheet****Manufacturer**

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

**Distributor**

Ultradent Products GmbH  
 Am Westhover Berg 30  
 51149 Cologne Germany  
 Email: infoDE@ultradent.com  
**Emergency Phone** : +49(0)2203-35-92-0

**1.4. Emergency telephone number**

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : F+,Xi

**R phrases** : R11,R36


**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Health** : Eye Irritation, Category 2


**Environmental** : Flammable Liquids, Category 2

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : F+ Xi



Extremely flammable



Irritant

**R&S statement(s)** : R11: Highly flammable.  
 R36: Irritating to eyes.



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**ULTRADENT**  
 PRODUCTS, INC.

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**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Hazard pictogram(s)** :    
 Flame Exclamation mark

**Signal Word** : WARNING

**Hazard statement(s)** : H225: Highly flammable liquid and vapour.  
 H319: Causes serious eye irritation.

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:  
 P351: Rinse cautiously with water for several minutes.  
 P315: Get immediate medical advice/attention.  
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
 P362+P364: Take off contaminated clothing and wash it before reuse.  
 P301: IF SWALLOWED:  
 P331: Do NOT induce vomiting.  
 P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P313: Get medical advice/attention.

**Storage** : P273: Avoid release to the environment.

**Disposal** : P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Physical hazards** : Flammable Liquid

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Methacryloxy propyl trimethoxy silane	7803-62-5	232-263-4	< 10	F+; R12; R17	Flam. Gas, Cat. 1; H220; H280; H332
Isopropyl Alcohol	67-63-0	200-661-7	< 95	F+; R11; R36/37/38; R22	Eye Irr., Cat. 2; Flam. Liq., Cat. 2; STOT SE, Cat. 3; H225; H319; H336

For full text of H-statements and R-phrases: see SECTION 16.

**SECTION 4: First aid measures**

**4.1. Description of first aid measures**

- Following eyes** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- Following skin** : Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- Following ingestion** : Give large volumes of water. Do not induce vomiting. Consult a physician if ingested in large amounts.
- Following inhalation** : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**

- Eyes** : Severe eye irritation
- Skin** : May cause slight irritation.
- Ingestion** : Irritating to mouth, throat, and stomach.
- Inhalation** : High concentrations in immediate area can displace oxygen and can cause dizziness, unconsciousness, and even death with longer exposure. Keep people away from such vapors without self-contained breathing apparatus.

**4.3. Indication of any immediate medical attention and special treatment needed**

- Notes to physician** : Not Applicable

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

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**Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

**Explosion hazards** : Not Determined

**Fire explosion** : Not Determined

**Sensitive to static discharge** : Not Determined

**Sensitivity to impact** : Not Determined

**5.3. Advice for firefighters**

**Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

**Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**Special protective equipment** : Wear suitable protective clothing, gloves and eye/face protection.

**6.2. Environmental precautions**

**Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

**6.3. Methods and material for containment and cleaning up**

**Small spill** : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

**Large spill** : Collect in tightly closed containers.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**Additional information** : Refer particularly to local circumstances and regulations.

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Keep away from heat, sparks and flame.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Dental Bonding Agent

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Not Determined

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**8.2. Exposure controls**

- Engineering controls** : Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.
- Eye/face protection** : Wear safety glasses with side shields (or goggles) and a face shield.
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Use only in well-ventilated areas.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

- Physical state** : Volatile Liquid
- Colour** : Colorless
- Odour** : Rubbing alcohol
- Melting temperature** : -89°C
- Boiling temperature** : 82°C
- Solubility in water** : Fully miscible

**9.2. Other information**

- Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

- Reactivity** : Stable

**10.2. Chemical stability**

- Chemical stability** : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

- Hazardous polymerization** : None

**10.4. Conditions to avoid**

- Conditions to avoid** : Heat, flames, and ignition sources

**10.5. Incompatible materials**

- Incompatible materials** : Strong oxidizers, acids, and Isocyanates

**10.6. Hazardous decomposition products**

- Hazardous decomposition products** : Complete combustion generates carbon dioxide. Incomplete combustion generates toxic and highly flammable carbon monoxide.

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

- Notes** : Device is biocompatible when used as directed by dental professionals

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per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Toxicity** : None Expected.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not Determined

**12.4. Mobility in soil**

**Mobility in soil** : Does not bioaccumulate.

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Not Determined

**12.6. Other adverse effects**

**Environmental data** : Not defined

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : 1987

**14.2. UN proper shipping name**

**UN proper shipping name** : Alcohols, n.o.s. (Isopropyl alcohol mixture)

**14.3. Transport hazard class(es)**

**Primary hazard class/division** : 3

**Hazard classification** : 3

**14.4. Packing group**

**Packing group** : II

**14.5. Environmental hazards**

**Marine pollutant #1** : N/A

**14.6. Special precautions for user**

**ADR - road** : N/A

**RID - rail** : N/A

**IMDG - sea** : N/A

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**IATA - air** : N/A

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : N/A

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R11: Highly flammable.  
 R12: Extremely flammable.  
 R17: Spontaneously flammable in air.  
 R22: Harmful if swallowed.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 Eye Irr., Cat. 2: Eye Irritation, Category 2  
 Flam. Gas, Cat. 1: Flammable Gases, Category 1  
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2  
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3  
 H220: Extremely flammable gas.  
 H225: Highly flammable liquid and vapour.  
 H280: Contains gas under pressure; may explode if heated.  
 H319: Causes serious eye irritation.  
 H332: Harmful if inhaled.  
 H336: May cause drowsiness or dizziness.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 08/07/2014 SDS. Revised: **Section 1:** Date-Revised.

**General statements** : N/A= Not Applicable

**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.