

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 10/31/2012  
SDS No : 5-001.13  
Date Revised : 11/28/2017  
Revision No : 12

## 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. Ultradent Drive (10200 South)  
South Jordan, UT 84095

##### EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

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

**Health** : Eye Irritation, Category 2  
Acute Toxicity (Inhalation), Category 1

**Environmental** : Flammable Liquids, Category 2

#### 2.2. Label elements

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

Hazard pictogram(s) :



Flame



Exclamation  
mark

**Signal Word** : DANGER

**Hazard statement(s)** : H225: Highly flammable liquid and vapour.  
H319: Causes serious eye irritation.  
H335: May cause respiratory irritation.

**Precautionary statement(s)**

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<b>Prevention</b>	: P280: Wear protective gloves/protective clothing/eye protection/face protection. P240: Ground and bond container and receiving equipment. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P243: Take action to prevent static discharges. P241: Use explosion-proof [electrical/ventilating/lighting/] equipment. P242: Use non-sparking tools.
<b>Response</b>	: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. 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. P370+P378: In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Storage</b>	: P403+P235: Store in a well-ventilated place. Keep cool.
<b>Disposal</b>	: P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

### 2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

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

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Check for and remove any contact lenses. In case of contact, immediately flush

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eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

- 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** : NAP

## SECTION 5: Fire fighting measures

### 5.1. Extinguishing media

- Extinguishing media** : Water spray, foam, dry chemical, and carbon dioxide (CO<sub>2</sub>)

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

- Hazardous combustion products** : Not available

### 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.

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

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**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**General procedures** : Avoid contact with eyes, skin and clothing.  
**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** : Isopropyl Alcohol CAS: 67-63-0

Control Parameters	Exposure Limits
OSHA PEL General Industry	400 ppm (980 mg/m <sup>3</sup> )
OSHA PEL Construction Industry	400 ppm (980 mg/m <sup>3</sup> )
OSHA PEL Shipyard Employment	400 ppm (980 mg/m <sup>3</sup> )
NIOSH REL	400 ppm (980 mg/m <sup>3</sup> ) TWA 500 ppm (1225 mg/m <sup>3</sup> ) STEL
ACGIH TLV (2003)	200 ppm (491 mg/m <sup>3</sup> ) TWA 400 ppm (984 mg/m <sup>3</sup> ) STEL
CAL/OSHA PELs	400 ppm (980 mg/m <sup>3</sup> ) TWA 500 ppm (1225 mg/m <sup>3</sup> )

Silane CAS: 7803-62-5

Control Parameters	Exposure Limits
ACGIH TLV	5 ppm, 6.6 mg/m <sup>3</sup>
OSHA PEL	none
NIOSH REL	5 ppm TWA

**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.

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### SECTION 9: Physical and chemical properties

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

Physical state	: Volatile liquid
Colour	: Colorless
Odour	: Rubbing alcohol
pH	: 5 - 8
Melting temperature	: -89°C
Boiling temperature	: 82°C
Flash point	: 18°C
Solubility in water	: Fully miscible

#### 9.2. Other information

Additional information	: No further relevant information available
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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Reactivity	: Stable
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#### 10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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#### 10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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#### 10.4. Conditions to avoid

Conditions to avoid	: Avoid heat, sparks, open flames and other ignition sources.
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#### 10.5. Incompatible materials

Incompatible materials	: Strong oxidizers, acids, and Isocyanates
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#### 10.6. Hazardous decomposition products

Hazardous decomposition products	: Complete combustion generates carbon dioxide. Incomplete combustion generates toxic and highly flammable carbon monoxide.
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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute

Dermal LD <sub>50</sub>	: > 13000 mg/kg Rabbit
Notes	: There are no components of unknown toxicity (dermal).
Oral LD <sub>50</sub>	: > 3800 mg/kg (mouse/rat/rabbit)
Notes	: There are no components of unknown toxicity (Oral).
Inhalation LC <sub>50</sub>	: > 70 ppm/4H (Rat)
Notes	: There are no components of unknown toxicity (inhalation).

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**Other information** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

**Mobility in soil** : Not available

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

**Results of PBT and vPvB assessment** : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

**Environmental data** : Do not flush to sewer.

**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** : NAP

**14.6. Special precautions for user**

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

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IATA - air : NAP

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

Transport in bulk : NAP

### SECTION 15: Regulatory information

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

**General information** : European Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC Substances.  
CAN: All of the raw materials listed in Section 3 are on the Candian DSL list.

**General comments** : 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 H-statements (number and full-text)** : 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), Central Nervous System 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 07/18/2016 SDS. Revised: **Section 1:** MSDS No. **Section 2:** . **Section 4:** EYES, NOTES TO PHYSICIAN. **Section 5:** EXTINGUISHING MEDIA. **Section 6:** . **Section 9:** COMMENTS, FLASHPOINT AND METHOD, PERCENT VOLATILE, pH. **Section 10:** CONDITIONS TO AVOID. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permittable exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**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,

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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.