

SAFETY DATA SHEET

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



Date Issued : 10/31/2012
SDS No : 5-001.14
Date Revised : 06/25/2018
Revision No : 13

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 1

2.2. Label elements

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

Hazard pictogram(s) :



Signal Word : DANGER

Hazard statement(s) : H319: Causes serious eye irritation.
H335: May cause respiratory irritation.
H224: Extremely flammable liquid and vapour.

Precautionary statement(s)

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| | |
|-------------------|--|
| Prevention | : 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. |
| Response | : 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. |
| Storage | : P403+P235: Store in a well-ventilated place. Keep cool. |
| Disposal | : 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 (CO₂)

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 ³) |
| OSHA PEL Construction Industry | 400 ppm (980 mg/m ³) |
| OSHA PEL Shipyard Employment | 400 ppm (980 mg/m ³) |
| NIOSH REL | 400 ppm (980 mg/m ³) TWA 500 ppm (1225 mg/m ³) STEL |
| ACGIH TLV (2003) | 200 ppm (491 mg/m ³) TWA 400 ppm (984 mg/m ³) STEL |
| CAL/OSHA PELs | 400 ppm (980 mg/m ³) TWA 500 ppm (1225 mg/m ³) |

Silane CAS: 7803-62-5

| Control Parameters | Exposure Limits |
|--------------------|------------------------------|
| ACGIH TLV | 5 ppm, 6.6 mg/m ³ |
| 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 | : 17°C |
| Solubility in water | : Fully miscible |

9.2. Other information

| | |
|------------------------|---|
| Additional information | : No further relevant information available |
|------------------------|---|

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 | : Avoid heat, sparks, open flames and other 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

| | |
|-----------------------------|---|
| Dermal LD ₅₀ | : > 13000 mg/kg Rabbit |
| Notes | : There are no components of unknown toxicity (dermal). |
| Oral LD ₅₀ | : > 3800 mg/kg (mouse/rat/rabbit) |
| Notes | : There are no components of unknown toxicity (Oral). |
| Inhalation LC ₅₀ | : > 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 11/28/2017 SDS. Revised: **Section 1**: MSDS No. **Section 9**: FLASHPOINT AND METHOD.

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, 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.