

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 16.01.2020

Revision: 03.12.2019

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** Silane
- **Article number:** 10325
- **Index number:** SDS 5-001.15
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Bonding Agent
- **Application of the substance / the mixture** Professional Dental Bonding Agent
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
-
- EC Responsible Person
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



Flam. Liq. 2 H225 Highly flammable liquid and vapour.



Eye Irrit. 2 H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** GHS02, GHS07

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- **Signal word** *Danger*

- **Hazard-determining components of labelling:**

Isopropyl Alcohol

- **Hazard statements**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

- **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P240 Ground/bond container and receiving equipment.

P241 Use explosion-proof electrical/ventilating/lighting equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P271 Use only outdoors or in a well-ventilated area.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340 IF INHALED: Remove person to fresh air and keep 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.

P312 Call a POISON CENTER/doctor if you feel unwell.

P337+P313 If eye irritation persists: Get medical advice/attention.

P370+P378 In case of fire: Use for extinction: CO₂, powder or water spray.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P403+P235 Store in a well-ventilated place. Keep cool.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 67-63-0	Isopropyl Alcohol	>50-≤100%
EINECS: 200-661-7	☠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319; STOT SE 3, H336	
CAS: 2530-85-0	Silane	>2.5-≤10%
EINECS: 219-785-8	⚠ Skin Irrit. 2, H315; ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

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4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Move to fresh air. If breathing is difficult, give oxygen. Perform artificial respiration if breathing has stopped. Get medical attention immediately.
- **After skin contact:**
Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention if symptoms occur. Take off immediately all contaminated clothing. Rinse skin with water [or shower].
- **After eye contact:**
Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
- **After swallowing:**
Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Carbon dioxide or dry powder. Water in large amounts. Alcohol resistant foam. Use fire-extinguishing media appropriate for surrounding materials.
- **Special hazards arising from the substance or mixture**
Heat may cause the containers to explode. Vapors may travel considerable distance to a source of ignition and flash back. Vapors may cause a flash fire or ignite explosively. Prevent buildup of vapors or gases to explosive concentrations.
- **Advice for firefighters:**
- **Protective equipment:**
Use water spray to keep fire-exposed containers cool. Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.
- **Additional information**
Use water spray to keep fire-exposed containers cool. Water may be ineffective in fighting the fire. Fight fire from a protected location. Move containers from fire area if you can do so without risk.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Use personal protective equipment. Keep unauthorized personnel away. Ventilate closed spaces before entering them. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Keep upwind.

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- **Environmental precautions:**
Do not contaminate water sources or sewer. Prevent further leakage or spillage if safe to do so.
- **Methods and material for containment and cleaning up:**
*All equipment used when handling the product must be grounded. Absorb spill with vermiculite or other inert material, then place in a container for chemical waste. Dike far ahead of larger spill for later recovery and disposal. In case of leakage, eliminate all ignition sources.
Dike for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Stop the flow of material, if this is without risk.*
- **Reference to other sections**
*See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.*

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**
*Flammable/combustible - Keep away from oxidizers, heat and flames.
Avoid contact with skin and eyes. Avoid breathing mists or vapors. Use only with adequate ventilation. Wash hands thoroughly after handling.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground and bond container and receiving equipment. Take precautionary measures against static discharges.*
- **Information about fire - and explosion protection:**
*Fumes can combine with air to form an explosive mixture.
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
*Provide ventilation for receptacles.
Store in a cool location.*
- **Information about storage in one common storage facility:** *Store away from oxidising agents.*
- **Further information about storage conditions:**
*Store receptacle in a well ventilated area.
Store in a cool place.
Protect from contamination.
Protect from heat
See product labelling.
Keep container tightly sealed.
Store in cool, dry conditions in well - sealed receptacles.*
- **Specific end use(s)** *Professional Dental Bonding Agent*

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** *No further data; see item 7.*

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- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

67-63-0 Isopropyl Alcohol	
WEL (Great Britain)	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm

- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Good general ventilation (typically 10 air changes per hour) should be used.

Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Use personal protective equipment as required.

Practice good housekeeping.

Use explosion-proof ventilation equipment.

Discard contaminated footwear that cannot be cleaned.

Routinely wash work clothing and protective equipment to remove contaminants.

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.

When using do not smoke.

Special rooms for washing, showering and changing are required.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

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· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Liquid
· Colour:	Colourless
· Odour:	Alcohol-like
· Odour threshold:	Not determined.

· **pH-value at 20 °C:** 5-8· **Change in condition**

· Melting point/freezing point:	-89 °C
· Initial boiling point and boiling range:	82 °C

· **Flash point:** 17 °C· **Flammability (solid, gas):** Not applicable.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product is not explosive. However, formation of explosive air/vapour mixtures are possible.· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.· **Density at 20 °C:** <1 g/cm³· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with water:**

Fully miscible.

· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Solvent content:**

· Organic solvents:	<95 %
· Water:	<5 %
· VOC (EC)	<95%

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· Other information

No further relevant information available.

10 Stability and reactivity

- **Reactivity Stable**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** Danger of explosion.
- **Conditions to avoid:**
 - Sparks
 - Flames
 - Ignition sources
 - Heat
- **Incompatible materials:**
 - Aldehydes
 - Alkalis
 - Amines
 - Isocyanates
 - Strong oxidizing agents
- **Hazardous decomposition products:** Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:**67-63-0 Isopropyl Alcohol**

Oral	LD50	3,600 mg/kg (mouse)
		4,710 mg/kg (rat)
		5,030 mg/kg (rabbit)
	LC50 Fish	9,640 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>12,800 mg/kg (rabbit)
Inhalative	LC50/4 h	26.5 mg/l (mouse)
		25.52 mg/l (rat)
		LC50 Crustacean
	LC50(Daphnia magna)	>1,000 mg/l (daphnia) (Toxicity to aquatic invertebrates)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
 - Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
 - May cause drowsiness or dizziness.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.**12 Ecological information**· **Toxicity**· **Aquatic toxicity:****67-63-0 Isopropyl Alcohol**

EC50 >1,000 mg/kg (Algae)

EC50 >100 mg/l (Fish)

· **Persistence and degradability** No further relevant information available.· **Behaviour in environmental systems:**· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.· **Additional ecological information:**· **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· **Results of PBT and vPvB assessment**· **PBT:** Not applicable.· **vPvB:** Not applicable.· **Other adverse effects** No further relevant information available.**13 Disposal considerations**· **Waste treatment methods**· **Recommendation** Do not allow product to reach sewage system.· **European waste catalogue**

HP3 Flammable

HP4 Irritant - skin irritation and eye damage

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **UN-Number**· **ADR, IMDG, IATA**

UN1993

· **UN proper shipping name**· **ADR**

1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))

· **IMDG, IATA**

FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))

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· Transport hazard class(es)

· ADR, IMDG, IATA



· Class

3 Flammable liquids.

· Label

3

· Packing group

II

· ADR, IMDG, IATA

· Environmental hazards:

Not applicable.

· Special precautions for user

Warning: Flammable liquids.

· Danger code (Kemler):

33

· EMS Number:

F-E, S-E

· Stowage Category

B

· Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ)

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· Transport category

2

· Tunnel restriction code

D/E

· IMDG

· Limited quantities (LQ)

1L

· Excepted quantities (EQ)

Code: E2

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":

UN 1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)), 3, II

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Seveso category P5c FLAMMABLE LIQUIDS

· Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

· Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

· REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

· Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

- H225 Highly flammable liquid and vapour.*
- H315 Causes skin irritation.*
- H319 Causes serious eye irritation.*
- H335 May cause respiratory irritation.*
- H336 May cause drowsiness or dizziness.*

· Department issuing SDS: Regulatory Affairs**· Contact: Customer Service****· Abbreviations and acronyms:**

- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*
- IMDG: International Maritime Code for Dangerous Goods*
- IATA: International Air Transport Association*
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals*
- EINECS: European Inventory of Existing Commercial Chemical Substances*
- ELINCS: European List of Notified Chemical Substances*
- CAS: Chemical Abstracts Service (division of the American Chemical Society)*
- VOC: Volatile Organic Compounds (USA, EU)*
- LC50: Lethal concentration, 50 percent*
- LD50: Lethal dose, 50 percent*
- PBT: Persistent, Bioaccumulative and Toxic*
- vPvB: very Persistent and very Bioaccumulative*
- Flam. Liq. 2: Flammable liquids – Category 2*
- Skin Irrit. 2: Skin corrosion/irritation – Category 2*
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2*
- STOT/SE 3: Specific target organ toxicity (single exposure) – Category 3*

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