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1 Identification

Other means of identification

· Trade name: Silane

· Article number: SDS 5-001.16R01, 10325, 10217

- · 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

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Ultradent Australia Pty Ltd.

Level 22/2 Market Street

Sydney NSW 2000

Australia

Email: info.anz@ultradent.com Toll Free: 1-800-290929

- · Further information obtainable from: Customer Service
- · Emergency telephone number:

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

2 Hazard(s) Identification

· Classification of the substance or mixture



Flammable liquids – Category 2 H225 Highly flammable liquid and vapour.



Eye damage/irritation – Category 2A

H319 Causes serious eye irritation.

Specific target organ toxicity (single exposure) –

H336 May cause drowsiness or dizziness.

Category 3

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS02, GHS07
- · Signal word Danger
- · Hazard-determining components of labelling:

Isopropyl Alcohol (>50-<100 %)

· Hazard statements

H225 Highly flammable liquid and vapour.

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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/sparks/open flames/hot surfaces. No smoking.
P241 Use explosion-proof electrical/ventilating/lighting equipment.

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

with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P405 Store locked up.

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

regulations.

3 Composition and Information on Ingredients

· Chemical characterisation: Mixtures

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

· Dangerous components:			
67-63-0	Isopropyl Alcohol	>50-<100%	
	♦ Flammable liquids – Category 2, H225; ♦ Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H336		
2530-85-0	Silane	>2.5-≤10%	
	♦ Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335		

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- General information: Immediately remove any clothing soiled by the product.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Immediately remove all soiled and contaminated clothing.

Immediately rinse with water.

· After eye contact:

Remove contact lenses, if present. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Call a physician if irritation develops or persists.

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: Rinse mouth with water.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- $\cdot \textit{Indication of any immediate medical attention and special treatment needed}$

No further relevant information available.

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5 Fire Fighting Measures

· 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.

· 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.

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Do not contaminate water sources or sewer. Prevent further leakage or spillage if safe to do so.

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· 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.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

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.

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Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

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.

· 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 and personal protection

- · Appropriate engineering controls No further data; see section 7.
- · Ingredients with limit values that require monitoring at the workplace:

67-63-0 Isopropyl Alcohol

WES Short-term value: 1230 mg/m³, 500 ppm Long-term value: 983 mg/m³, 400 ppm

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

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· 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.

· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 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 Highly flammable. • Decomposition temperature: Not determined.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of explosive air/vapour

mixtures are possible.

· Explosion limits:

Laptosion times.

Lower:

Upper:

Not determined.

Not determined.

Not determined.

Not determined.

Not determined.

Vapour pressure:
Vapour gensity at 20 °C:
Relative density
Not determined.
Not determined.
Not determined.
Not determined.
Not determined.

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· 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.

· Other information None

• Particle characteristics Not applicable.

· Physical state Fluid

10 Stability and Reactivity

· Reactivity Stable

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: Danger of explosion.
- · Conditions to avoid:

Flames

Sparks

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 3,600 mg/kg (mouse) Oral LD50 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 278 mg/l (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.

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- · 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.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity:

67-63-0 Isopropyl Alcohol

EC50 >100 mg/kg (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

Can be disposed of with household garbage after consulting with the waste disposal facility operator and the pertinent authorities and adhering to the necessary technical regulations.

Dispose of contents/container in accordance with international, federal, state, and local regulations.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADG, IMDG, IATA	UN1993
· UN proper shipping name · ADG · IMDG, IATA	1993 FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL)) FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))

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· Transport hazard class(es)

· ADG, IMDG, IATA



· Class 3 Flammable liquids.

· Label

· Packing group

· ADG, IMDG, IATA

• Environmental hazards: Not applicable.

· Special precautions for user Warning: Flammable liquids.

Hazard identification number (Kemler code):
 EMS Number:
 Stowage Category
 33
 F-E,S-E
 B

· Transport in bulk according to Annex II of Marpol

and the IBC Code Not applicable.

· Transport/Additional information:

 \cdot ADG

· 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
 Tunnel restriction code

D/E

· IMDG

Limited quantities (LQ)

· 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

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Australian Inventory of Industrial Chemicals

All ingredients are listed.

Standard for the Uniform Scheduling of Medicines and Poisons

64-19-7 Acetic Acid S2, S5, S6

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

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· 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
- · Chemical safety assessment:

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

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 from Section 3

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: Environmental, Health, and Safety
- · Contact: Customer Service
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

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)

 $LC 50: Lethal\ concentration,\ 50\ percent$

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

Flammable liquids – Category 2: Flammable liquids – Category 2 Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2

Eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Specific target organ toxicity (single exposure) – Category 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.

ΔΙΙ