

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

Printing date 04.06.2019

Revision: 04.06.2019

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

- **Product identifier**
- **Trade name:** Ultradent™ Universal Dentin Sealant
- **Article number:** 10344
- **Index number:** SDS 142-001.06
- **Relevant identified uses of the substance or mixture and uses advised against** Professional Dentin Sealant
- **Application of the substance / the mixture** Professional Dentin Sealant
- **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.

- **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
- **Signal word** Danger
- **Hazard statements**
H225 Highly flammable liquid and vapour.
- **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.

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- 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.*
- 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.*
- 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: 64-17-5	Ethyl Alcohol	 Flam. Liq. 2, H225	60-70%
EINECS: 200-578-6			

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

4 First aid measures

- **Description of first aid measures**
- **General information:**
Show this safety data sheet to the doctor in attendance. When symptoms persist or in all cases of doubt seek medical advice.
Immediately remove any clothing soiled by the product.
- **After inhalation:**
Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration. Consult a physician.
- **After skin contact:**
Wash off immediately with soap and plenty of water. Remove all contaminated clothes and shoes. Use a mild soap if available. Call a physician if irritation develops or persists.
- **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.
- **After swallowing:**
Rinse mouth with water and afterwards drink plenty of water or milk. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Get medical attention immediately.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
See Section 2.2, Label Elements and/or Section 11, Toxicological effects.
- **Indication of any immediate medical attention and special treatment needed** Treat symptomatically.

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5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use water spray, fog, carbon dioxide (CO₂), foam or dry chemical.
- **Special hazards arising from the substance or mixture**
*Hazardous decomposition products formed under fire conditions. Flash back possible over considerable distance.
 Hazardous Combustion Products: No information available.
 Explosion Data:
 Sensitivity to Mechanical Impact: None.
 Sensitivity to Static Discharge: None.*
- **Advice for firefighters:**
- **Protective equipment:**
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
*Ensure adequate ventilation, especially in confined areas. Remove all sources of ignition. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe vapors or spray mist.
 Wear protective equipment. Keep unprotected persons away.*
- **Environmental precautions:**
*Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Do not allow material to contaminate ground water system. See Section 12 for additional Ecological information.
 Dilute with plenty of water.
 Do not allow to enter sewers/ surface or ground water.*
- **Methods and material for containment and cleaning up:**
*Methods for Containment: Prevent further leakage or spillage if safe to do so.
 Methods for cleaning up: Pick up and transfer to properly labeled containers
 Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
 Dispose contaminated material as waste according to item 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:**
*Advice on safe handling: Keep containers tightly closed in a dry, cool and well-ventilated place.
 Hygiene measures: When using, do not eat, drink or smoke. Wash hands before breaks and at the end of workday. Remove and wash contaminated clothing before re-use.*
- **Information about fire - and explosion protection:**
*Keep ignition sources away - Do not smoke.
 Protect against electrostatic charges.*

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- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
*Storage Conditions: Keep locked up or in an area accessible only to qualified or authorized persons. Store between 41 and 77 °F (5 - 25° C) in a dry, well ventilated place away from sources of heat, ignition and direct sunlight. Store in original container.
 Store in a cool location.*
- **Information about storage in one common storage facility:** *Not required.*
- **Further information about storage conditions:**
*See product labelling.
 Keep container tightly sealed.*
- **Specific end use(s)** *Professional Dentil Sealant*

8 Exposure controls/personal protection

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

- **Control parameters**

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

64-17-5 Ethyl Alcohol
WEL (Great Britain) Long-term value: 1920 mg/m ³ , 1000 ppm

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

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Engineering Measures: Ensure adequate ventilation, especially in confined areas.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

- **Respiratory protection:**

If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Respiratory protection must be provided in accordance with current local regulations.

- **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:**
Safety glasses with side shields.



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:	Yellow-brown
· Odour:	Pleasant
· Odour threshold:	Not determined.

· pH-value:	Not determined.
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· Change in condition

· Melting point/freezing point:	-114 °C
· Initial boiling point and boiling range:	78 °C

· Flash point:	11 °C
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· Flammability (solid, gas):	Not applicable.
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· Decomposition temperature:	Not determined.
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· Auto-ignition temperature:	Product is not selfigniting.
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· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
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· Explosion limits:

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

· Vapour pressure at 20 °C:	59.6 hPa
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· Density at 20 °C:	0.916-1.02 g/cm ³
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· Relative density	Not determined.
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· Vapour density at 20 °C	1.59 g/cm ³
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· Evaporation rate	Not determined.
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· Solubility in / Miscibility with water:

Fully miscible.

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

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

· Solvent content:

· VOC (EC)	0.00 %
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· Solids content:	≤40.0 %
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· Other information

No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** Stable under recommended storage conditions
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Contact with acetyl chloride and a wide range of oxidizers.
- **Incompatible materials:** Strong oxidizing agents
- **Hazardous decomposition products:** Carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke).

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:**64-17-5 Ethyl Alcohol**

Oral	LD50	5,600 mg/kg (Guinea pig)
		3,400 mg/kg (mouse)
		7,060 mg/kg (rat)
Inhalative	LC50 Fish	>10,000 mg/l (Fish)
	LC50/4 h	39 mg/l (mouse) 20,000 mg/l (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Product Information
 - May cause irritation and defatting of skin on prolonged contact.
 Component Information
 - No information available
- **Serious eye damage/irritation**
Product Information
 - Liquid or vapor may cause irritation.
 Component Information
 - No information available
- **Respiratory or skin sensitisation**
Product Information
 - Exposure to over 1000 ppm may cause headache, drowsiness, vomiting, coughing, dizziness or stupor.
 Component Information
 - No information available
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity**
Product Information
 - No information available
 Component Information
 - No information available
- **Carcinogenicity**
Product Information
 - The table below indicates whether each agency has listed any ingredient as a carcinogen
 Component Information

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- There are no known carcinogenic chemicals in this product
- **Reproductive toxicity**
Product Information
 - No information available
 Component Information
 - No information available
- **STOT-single exposure** No information available
- **STOT-repeated exposure**
May cause adverse liver effects
Contains a known or suspected reproductive toxin
- **Aspiration hazard**
Product information
 - No information available
 Component information
 - No information available
 Other adverse effects
Product Information
 - Ingestion can cause depression of central nervous system, vomiting, nausea and diarrhea.
 Component Information
 - No information available
 Aspiration hazard
Product Information
 - No information available
 Component Information
 - No information available

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

64-17-5 Ethyl Alcohol	
Algae Toxicity	1,000 mg/l (Algae)

- **Persistence and degradability** No information available

- **Behaviour in environmental systems:**

- **Bioaccumulative potential**

Discharge into the environment must be avoided

Chemical Name	log Pow
Ethanol	-0.32
64-17-5	

- **Mobility in soil** No 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** Discharge into the environment must be avoided

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13 Disposal considerations

- **Waste treatment methods**

- **Recommendation**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Do not allow product to reach sewage system.

- **European waste catalogue**

HP 3	Flammable
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- **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**

- **ADR, IMDG, IATA** UNI866

- **UN proper shipping name**

- **ADR** 1866 RESIN SOLUTION
- **IMDG, IATA** RESIN SOLUTION

- **Transport hazard class(es)**

- **ADR, IMDG, IATA**



- **Class** 3 Flammable liquids.
- **Label** 3

- **Packing group**

- **ADR, IMDG, IATA** II

- **Environmental hazards:** Not applicable.

- **Special precautions for user**

- **Danger code (Kemler):** 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)** 5L

- **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

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· IMDG	
· Limited quantities (LQ)	5L
· 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 1866 RESIN SOLUTION, 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

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.
- **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

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