

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/25/2007

SDS No : 142-001.4

Date Revised : 05/05/2015

Revision No : 3

Universal Dentin Sealant

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : UD/ 10344
Product name : Universal Dentin Sealant
Product description : Professional Dentin Sealant Material

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dentin Sealant Material

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

Distributor

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 Directive 1999/45/EC

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

Danger symbols : F,Xi

R phrases : R11,R22,R36

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

Health : Eye Irritation, Category 2
 Acute Toxicity (Oral), Category 4

Environmental : Flammable Liquids, Category 2

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : F Xi



Highly flammable



Irritant

R&S statement(s) : R11: Highly flammable.

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R22: Harmful if swallowed.

R36: Irritating to eyes.

Classification according to Regulation (EC) No 1272/2008 [CLP]**Hazard pictogram(s)**

:



Flame

Exclamation
mark**Signal Word**

: WARNING

Hazard statement(s)

: H225: Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

H302: Harmful if swallowed.

Precautionary statement(s)**Prevention**

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

Response

: P305: IF IN EYES:

P351: Rinse cautiously with water for several minutes.

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

P301: IF SWALLOWED:

P310: Immediately call a POISON CENTER or doctor/physician.

P330: Rinse mouth.

P331: Do NOT induce vomiting.

Storage

: P273: Avoid release to the environment.

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

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

2.3. Other hazards**Immediate concerns**

: Flammable

SECTION 3: Composition / information on ingredients**3.1. Substances**

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Ethyl Alcohol	64-17-5	200-578-6	< 40	F; R11	Flam. Liq., Cat. 2; H225
Shellac	9000-59-3	232-549-9	< 80	Xi; R36/37/38; R22	Acute Tox. (O), Cat. 4; Skin Irr., Cat. 2; Eye Irr., Cat. 2; STOT SE, Cat. 3; H315; H319; H335; H302

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Immediately flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.
- Following skin** : Not needed for normal use.
- Following ingestion** : If swallowed, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : Irritating to eyes.
- Skin** : May cause slight irritation.
- Ingestion** : Harmful if swallowed.
- Inhalation** : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

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Extinguishing media : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

Explosion hazards : Not Determined

Fire explosion : Not Determined

Sensitive to static discharge : Not Determined

Sensitivity to impact : Not Determined

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.

Fire fighting equipment : Foam, dry chemical, carbon dioxide (CO₂).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

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 : Remove all sources of ignition. Ventillate area of leak or spill. Pick up spill for recovery or disposal and place into sealed containers.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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 Sealant

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

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8.2. Exposure controls

- Eye/face protection** : Wear eye protection
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Liquid
- Colour** : Yellow
- Odour** : Ethanol

9.2. Other information

- Percent volatile** : Not Determined

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** : Acetyl Chloride and a wide range of oxidizers.

10.5. Incompatible materials

- Incompatible materials** : Strong oxidizers

10.6. Hazardous decomposition products

- Hazardous decomposition products** : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

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

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

- 96-hour LC₅₀** : Not Determined

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48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Biodegradable

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. (Ethyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

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Transport in bulk : N/A

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

RoHS : 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 R-phrases and/or H-statements (number and full text) : R11: Highly flammable.
 R22: Harmful if swallowed.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H225: Highly flammable liquid and vapour.
 H302: Harmful if swallowed.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 05/28/2014 SDS. Revised: **Section 1:**
 . **Section 2:** . **Section 4:** INGESTION. **Section 8:** PERSONAL
 PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS
 POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat),
 INHALATION LC₅₀ (rat) ACUTE. **Section 15:** SECTION 15: Regulatory
 information. **Section 16:** GENERAL STATEMENTS.

General statements : N/A= Not Applicable

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.