

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 10/31/2006  
SDS No : 67-001.7  
Date Revised : 09/19/2016  
Revision No : 6

## Composite Wetting Resin

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

#### 1.1. Product identifier

**Product code** : CW/13575  
**Product name** : Composite Wetting Resin  
**Product description** : Liquid resin for adaptation of composite restoration and preparation

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

**Relevant identified uses** : Professional Dental Composite Facilitating Agent

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Ultradent Products, Inc.  
505 W. 10200 S.  
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 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** : Xi

**R phrases** : R36/38

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

**Health** : Skin Irritation, Category 2  
Skin Sensitization, Category 1  
Eye Irritation, Category 2

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : Xi



Irritant

**R& statement(s)** : R36/38: Irritating to eyes and skin.

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


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<b>Hazard pictogram(s)</b>	:	 Exclamation mark
<b>Signal Word</b>	:	WARNING
<b>Hazard statement(s)</b>	:	H317: May cause an allergic skin reaction. H315: Causes skin irritation. H319: Causes serious eye irritation.
<b>Precautionary statement(s)</b>	:	
<b>Prevention</b>	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	:	P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P302+P352: IF ON SKIN: Wash with plenty of soap and water. P332+P313: If skin irritation occurs: Get medical advice/attention.
<b>Storage</b>	:	P273: Avoid release to the environment.
<b>Disposal</b>	:	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 Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43	Skin Sens.,Cat. 1B; H317
Bis-GMA	1565-94-2	216-367-7	< 20	Xi; R22; R36/37/38	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1; H315; H317; H319

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Following eyes</b>	:	Hold eyelids apart and flush eyes with plenty of water for at least 5 minutes. Get medical attention if irritation develops or persists.
<b>Following skin</b>	:	Wash with soap and water. Get medical attention if irritation develops or persists.

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**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

**Eyes** : May be mildly irritating to eyes.

**Skin** : May cause skin irritation and sensitization.

**Ingestion** : Maybe harmful if swallowed in large quantities.

**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**

**Extinguishing media** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

**5.2. Special hazards arising from the substance or mixture**

**Hazardous combustion products** : None known.

**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**

**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** : Absorb with inert, damp non-combustible material, then flush area with water.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**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 sources and direct sunlight.

**Storage** : See product labeling.

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**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 Composite Facilitating Agent

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : None

**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** : Low viscosity liquid

**Colour** : Slight yellow tint

**Odour** : Acrylic

**pH** : NAP (non-aqueous)

**Specific gravity** : 1.5 to 1.6

**9.2. Other information**

**Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

**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** : Light exposure

**10.5. Incompatible materials**

**Incompatible materials** : Not Determined

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : None known.

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute

- Dermal LD<sub>50</sub>** : > 2000 mg/kg mouse/rat
- Notes** : ~81% of the mixture consists of components of unknown toxicity (dermal).
- Oral LD<sub>50</sub>** : > 2500 mg/kg Rat/Mouse
- Notes** : ~62% of the mixture consists of components of unknown toxicity (oral).
- Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.
- 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 allow to enter sewers or drains that may lead to waterways.

### 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** : NAP

#### 14.2. UN proper shipping name

- UN proper shipping name** : Not Dangerous Goods

#### 14.3. Transport hazard class(es)

- Hazard classification** : NAP

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**Composite Wetting Resin**

**14.4. Packing group**

Packing group : NAP

**14.5. Environmental hazards**

Marine pollutant #1 : NAP

**14.6. Special precautions for user**

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

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 comments : Please refer to Medical Devices Directive 93/42/EEC.

**15.2. Chemical safety assessment**

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.  
This product is not considered dangerous for transportation.

**SECTION 16: Other information**

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.  
R36/37/38: Irritating to eyes, respiratory system and skin.  
R43: May cause sensitization by skin contact.  
Eye Irr., Cat. 2B: Eye Irritation, Category 2B  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/27/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INGESTION, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INHALATION, SKIN ). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** COLOR, pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 10:** CONDITIONS TO

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AVOID. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**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.