

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/31/2006

SDS No : 67-001.6

Date Revised : 04/27/2015

Revision No : 5

**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

**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** : Xi

**R phrases** : R36/38

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

**Health** : Skin Sensitization  
 Eye Irritation

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

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


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

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**ULTRADENT**  
 PRODUCTS, INC.

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**Composite Wetting Resin**

|                                   |   |   |
|-----------------------------------|---|---|
| <b>Hazard pictogram(s)</b>        | : | <br>Exclamation<br>mark  |
| <b>Signal Word</b>                | : | WARNING   |
| <b>Hazard statement(s)</b>        | : | H317: May cause an allergic skin reaction.<br>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:.<br>P351: Rinse cautiously with water for several minutes.<br>P332+P313: If skin irritation occurs: Get medical advice/attention.<br>P301: IF SWALLOWED:.<br>P310: Immediately call a POISON CENTER/doctor/...<br>P330: Rinse mouth.<br>P331: Do NOT induce vomiting.<br>P304: IF INHALED:.<br>P315: Get immediate medical advice/attention.<br>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| <b>Storage</b>                    | : | P273: Avoid release to the environment.   |
| <b>Disposal</b>                   | : | P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)   |

**2.3. Other hazards**

**Immediate concerns** : None

**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] |
|-----------------------------------|-----------|------------|-------|--|--|
| Triethylene Glycol Dimethacrylate | 109-16-0  | 203-652-6  | < 20  | Xi; R43  | H317   |
| Bis GMA                           | 1565-94-2 | 216-367-7  | < 20  | Xi;<br>R36/37/38;<br>R22                         | H302; H315;<br>H317; H318;<br>H335; H412                       |

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** : Hold eyelids apart and flush eyes with plenty of water for at least 5 minutes. Get medical attention If irritation develops or persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed, rinse mouth with water, 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** : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

- Eyes** : May be mildly irritating to eyes.
- Skin** : May cause sensitization to skin.
- Ingestion** : May be harmful if swallowed.
- Inhalation** : Maybe harmful if inhaled.

**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** : Please see Fire Fighting Equipment under Section 5.3.

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

- Hazardous combustion products** : None known.
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined

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**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 (CO<sub>2</sub>).

**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**

**Handling** : Keep away from heat sources and direct sunlight.

**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 Composite Facilitating Agent

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

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : In case of insufficient ventilation, wear suitable respiratory equipment.

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**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

**Physical state** : Liquid  
**Colour** : Yellow  
**Odour** : Acrylic

**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** : Not Determined

**10.5. Incompatible materials**

**Incompatible materials** : Not Determined

**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 LC<sub>50</sub>** : Not Determined  
**48-hour EC<sub>50</sub>** : Not Determined  
**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

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**Composite Wetting Resin****Persistence and degradability** : Not Established**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** : No data available.**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** : N/A**14.2. UN proper shipping name****UN proper shipping name** : Not Dangerous Goods**14.3. Transport hazard class(es)****Hazard classification** : N/A**14.4. Packing group****Packing group** : N/A**14.5. Environmental hazards****Marine pollutant #1** : N/A**14.6. Special precautions for user****ADR - road** : Not Dangerous Goods**RID - rail** : Not Dangerous Goods**IMDG - sea** : Not Dangerous Goods**IATA - air** : Not Dangerous Goods**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code****Transport in bulk** : Not Dangerous Goods**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

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**Composite Wetting Resin****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)** : R22: Harmful if swallowed.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 R43: May cause sensitization by skin contact.  
 H302: Harmful if swallowed.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H318: Causes serious eye damage.  
 H335: May cause respiratory irritation.  
 H412: Harmful to aquatic life with long lasting effects.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 10/22/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ACUTE. **Section 14:** VESSEL (IMO/IMDG) ( MARINE POLLUTANT #2 ). **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.