

**Safety Data Sheet**  
acc. to OSHA HCS

Printing date 07/08/2022

Reviewed on 07/07/2022

**1 Identification**

- **Product identifier**
- **Trade name:** *UltraTemp™ REZ II - Catalyst (Regular, Fast)*
- **Article number:** *SDS 439-001.02, 1007965, 1007604*
- **Application of the substance / the mixture** *Professional Dental Luting & Filling 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  
onlineordersupport@ultradent.com*
- **Information department:** *Customer Service*
- **Emergency telephone number:**  
*CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887*

**2 Hazard(s) identification**

- **Classification of the substance or mixture**



*GHS08 Health hazard*

*Carcinogenicity 2 H351 Suspected of causing cancer.*



*GHS07*

*Sensitization - Skin 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS07, GHS08*
- **Signal word** *Warning*
- **Health Hazard-determining components of labeling:**  
*Triethylene Glycol Dimethacrylate*
- **Hazard statements**  
*H317 May cause an allergic skin reaction.  
H351 Suspected of causing cancer.*
- **Precautionary statements**  
*P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P261 Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 If on skin: Wash with plenty of water.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P321 Specific treatment (see on this label).*

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P333+P313 *If skin irritation or rash occurs: Get medical advice/attention.*

P363 *Wash contaminated clothing before reuse.*

P405 *Store locked up.*

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 1

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1

Fire = 1

Reactivity = 0

### 3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

|             |                                   |           |
|-------------|-----------------------------------|-----------|
| 109-16-0    | Triethylene Glycol Dimethacrylate | >10-≤25%  |
| 112926-00-8 | Synthetic Amorphous Silica        | >10-≤25%  |
|             | Trade Secret                      | 1-10%     |
| 99-97-8     | Dimethyl-p-toluidine              | ≥0.1-<10% |

· **Additional information:**

*The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.*

### 4 First-aid measures

· **Description of first aid measures**

· **After inhalation:**

*Supply fresh air and to be sure call for a doctor.*

*In case of unconsciousness place patient stably in side position for transportation.*

· **After skin contact:** *Immediately wash with water and soap and rinse thoroughly.*

· **After eye contact:** *Rinse opened eye for several minutes under running water.*

· **After swallowing:** *If symptoms persist consult doctor.*

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

· **Indication of any immediate medical attention and special treatment needed**

*No further relevant information available.*

### 5 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** *Use fire fighting measures that suit the environment.*

· **Special hazards arising from the substance or mixture** *No further relevant information available.*

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
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**  
Ensure good ventilation/exhaustion at the workplace.  
Open and handle receptacle with care.  
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
See product labelling.  
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Luting & Filling Agent

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the remaining constituent has no known exposure limits.

### 112926-00-8 Synthetic Amorphous Silica

|     |   |
|-----|---|
| PEL | 20mppcf or 80mg/m <sup>3</sup> /%SiO <sub>2</sub>               |
| REL | Long-term value: 6 mg/m <sup>3</sup><br>See Pocket Guide App. C |
| TLV | TLV withdrawn   |

### Trade Secret

|     |   |
|-----|---|
| TWA | Short-term value: 0.8 mg/m <sup>3</sup> |
|-----|---|

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## 99-97-8 Dimethyl-p-toluidine

WEEL Long-term value: 0.5 ppm

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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 is based 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:** Goggles recommended during refilling.

· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

|                          |                                    |
|--------------------------|------------------------------------|
| · <b>Form:</b>           | Viscous liquid                     |
| · <b>Color:</b>          | According to product specification |
| · <b>Odor:</b>           | Characteristic                     |
| · <b>Odor threshold:</b> | Not determined.                    |

· **pH-value:** Not applicable (non-aqueous)

· **Change in condition**

|                                       |               |
|---------------------------------------|---------------|
| · <b>Melting point/Melting range:</b> | Undetermined. |
| · <b>Boiling point/Boiling range:</b> | >250 °C       |

· **Flash point:** >150 °C

· **Flammability (solid, gaseous):** Not applicable.

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|   |   |
|---|---|
| · <b>Ignition temperature:</b>                    | 255 °C  |
| · <b>Decomposition temperature:</b>               | Not determined.                               |
| · <b>Auto igniting:</b>                           | Product is not selfigniting.                  |
| · <b>Danger of explosion:</b>                     | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                        |   |
| <b>Lower:</b>                                     | Not determined.                               |
| <b>Upper:</b>                                     | Not determined.                               |
| · <b>Vapor pressure at 20 °C:</b>                 | 0 hPa   |
| · <b>Density at 20 °C:</b>                        | 1.65-1.75 g/cm <sup>3</sup>                   |
| · <b>Relative density</b>                         | Not determined                                |
| · <b>Vapor density</b>                            | Not determined.                               |
| · <b>Evaporation rate</b>                         | Not determined.                               |
| · <b>Solubility in / Miscibility with Water:</b>  | Not miscible or difficult to mix.             |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                               |
| · <b>Viscosity:</b>                               |   |
| <b>Dynamic:</b>                                   | Not determined.                               |
| <b>Kinematic:</b>                                 | Not determined                                |
| · <b>Solvent content:</b>                         |   |
| <b>VOC content:</b>                               | 0.10 %  |
|   | 1.7-1.8 g/l / 0.01 lb/gal                     |
| <b>VOC (EC)</b>                                   | 0.10 %  |
| <b>Solids content:</b>                            | 50.0 %  |
| · <b>Other information</b>                        | No further relevant information available.    |

## 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

|   |          |                  |
|---|----------|------------------|
| · <b>LD/LC50 values that are relevant for classification:</b> |          |                  |
| <b>ATE (Acute Toxicity Estimate)</b>                          |          |                  |
| Oral  | LD50     | 100,000 mg/kg    |
| Dermal  | LD50     | >2,000,000 mg/kg |
| Inhalative  | LC50/4 h | 3.51 mg/l        |

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### 109-16-0 Triethylene Glycol Dimethacrylate

|        |           |                                     |
|--------|-----------|-------------------------------------|
| Oral   | LD50      | >5,000 mg/kg (rat)                  |
|        | LC50 Fish | 16.4 mg/l (Fish) (Toxicity to fish) |
| Dermal | LD50      | >2,000 mg/kg (mouse)                |

### 112926-00-8 Synthetic Amorphous Silica

|        |      |                       |
|--------|------|-----------------------|
| Oral   | LD50 | >5,000 mg/kg (rat)    |
| Dermal | LD50 | >5,000 mg/kg (rabbit) |

### Trade Secret

|            |           |   |
|------------|-----------|---|
| Oral       | LD50      | >15,000 mg/kg (mouse)<br>>3,300 mg/kg (rat) |
|            | LC50 Fish | >10,000 mg/l (Fish) (Toxicity to fish)      |
| Dermal     | LD50      | >5,000 mg/kg (rabbit)                       |
| Inhalative | LC50/4 h  | 0.139 mg/l (rat)                            |

### 99-97-8 Dimethyl-p-toluidine

|            |           |                       |
|------------|-----------|-----------------------|
| Oral       | LC50 Fish | 46-52 mg/l (Fish)     |
| Dermal     | LD50      | >2,000 mg/kg (rabbit) |
| Inhalative | LC50/4 h  | 1.4 mg/l (rat)        |

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

|            |                       |    |
|------------|-----------------------|----|
| 13760-80-0 | Ytterbium Trifluoride | 3  |
| 99-97-8    | Dimethyl-p-toluidine  | 2B |

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

### 109-16-0 Triethylene Glycol Dimethacrylate

|                  |  |
|------------------|--|
| EC50             | >100 mg/kg (Algae)                                   |
| Biodegradability | 28 days (Aerobic) (Biodegradability testing)         |
| Aqua toxicity    | 32 mg/l (daphnia) (No Observed Effect Concentration) |

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|      |                        |
|------|------------------------|
| EC50 | >1,000 mg/kg (daphnia) |
|------|------------------------|

- **Persistence and degradability** No further relevant information available.

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- **Behavior 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 2 (Self-assessment): hazardous for water*  
*Do not allow product to reach ground water, water course or sewage system.*  
*Danger to drinking water if even small quantities leak into the ground.*
- **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:**  
*Dispose of contents/container in accordance with international, federal, state, and local regulations.*
- **Uncleaned packagings:**
- **Recommendation:** *Disposal must be made according to official regulations.*

## 14 Transport information

|   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>DOT, IMDG, IATA</b>  | Not Regulated   |
| · <b>UN proper shipping name</b>  |                 |
| · <b>DOT, IMDG, IATA</b>  | Not Regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>DOT, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | Not Regulated   |
| · <b>Packing group</b>  |                 |
| · <b>DOT, IMDG, IATA</b>  | Not Regulated   |
| · <b>Environmental hazards:</b>   | Not Applicable. |
| · <b>Special precautions for user</b>   | Not Applicable  |
| · <b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> | Not Applicable. |
| · <b>UN "Model Regulation":</b>   | Not Regulated   |

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**  
*No further relevant information available.*
- **Sara**

- **Section 355 (extremely hazardous substances):**  
*None of the ingredients is listed.*

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· **Section 313 (Specific toxic chemical listings):**

|           |            |
|-----------|------------|
| 1314-13-2 | Zinc Oxide |
|-----------|------------|

· **TSCA (Toxic Substances Control Act):**

|          |                                   |        |
|----------|-----------------------------------|--------|
| 109-16-0 | Triethylene Glycol Dimethacrylate | ACTIVE |
| 99-97-8  | Dimethyl-p-toluidine              | ACTIVE |

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

|         |                      |
|---------|----------------------|
| 99-97-8 | Dimethyl-p-toluidine |
|---------|----------------------|

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

|           |            |          |
|-----------|------------|----------|
| 1314-13-2 | Zinc Oxide | D, I, II |
|-----------|------------|----------|

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

|            |                       |    |
|------------|-----------------------|----|
| 13760-80-0 | Ytterbium Trifluoride | A4 |
|------------|-----------------------|----|

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

None of the ingredients is listed.

· **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.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 07/08/2022 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

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*PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit**Sensitization - Skin 1: Skin sensitisation – Category 1**Carcinogenicity 2: Carcinogenicity – Category 2**\* Data compared to the previous version altered.*

US