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

- Product identifier
  - Trade name: UltraTemp® REZ Catalyst- Regular and Fast
  - Article number: 15093, 15094
  - Index number: SDS 202-001.05
  - Relevant identified uses of the substance or mixture and uses advised against
    Professional Dental Non-Eugenol Temporary Luting & Filling Agent
  - Application of the substance / the mixture
    Professional Dental Non-Eugenol Temporary 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@utradent.com

  - 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

- Further information obtainable from:
  - 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
    
    ![GHS09 environment](image)
    Aquatic Acute 1  **H400** Very toxic to aquatic life.
    Aquatic Chronic 1  **H410** Very toxic to aquatic life with long lasting effects.

    ![GHS07](image)
    Skin Sens. 1  **H317** May cause an allergic skin reaction.

- Label elements
  - Labelling according to Regulation (EC) No 1272/2008
    The product is classified and labelled according to the CLP regulation.

(Contd. on page 2)
· Hazard pictograms

![GHS07][1] ![GHS09][2]

· Signal word Warning

· Hazard-determining components of labelling:
  Triethylene Glycol Dimethacrylate

· Hazard statements
  H317 May cause an allergic skin reaction.
  H410 Very toxic to aquatic life with long lasting effects.

· 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.
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P273 Avoid release to the environment.
  P280 Wear protective gloves.
  P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
  P321 Specific treatment (see on this label).
  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.

| CAS: 1314-13-2 | Zinc Oxide | >25-≤50% |
| EINECS: 215-222-5 | | |
| CAS: 112926-00-8 | Synthetic Amorphous Silica | >10-≤25% |
| EC number: 601-214-2 | | |
| CAS: 109-16-0 | Triethylene Glycol Dimethacrylate | >10-≤25% |
| EINECS: 203-652-6 | | |
| CAS: 99-97-8 | Dimethyl-p-toluidine | ≤2.5% |
| EINECS: 202-805-4 | | |

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

### 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.

(Contd. on page 3)
47.0.1

- **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 **Firefighting measures**

- **Extinguishing media**
  - **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
  - **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
  - **Protective equipment:** No special measures required.

6 **Accidental release measures**

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:**
  - Inform respective authorities in case of seepage into water course or sewage system.
  - 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).
- **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:** No special precautions are necessary if used correctly.
  - **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** See product labeling.
  - **Information about storage in one common storage facility:** Not required.
  - **Further information about storage conditions:** See product labelling.
- **Specific end use(s) Professional Dental Non-Eugenol Temporary Luting & Filling Agent**

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:**
  - The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
· Exposure controls
· Personal protective equipment:
· General protective and hygienic measures:
  Immediately remove all soiled and contaminated clothing
  Wash hands before breaks and at the end of work.
· Respiratory protection: Not required.
· 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.

· 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:
    Form: Viscous Liquid
    Colour: Beige
  · Odour: Acrylic
  · Odour threshold: Not determined.

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

· Change in condition
  Melting point/freezing point: Undetermined.
  Initial boiling point and boiling range: >250 °C

· Flash point: >150 °C

· Flammability (solid, gas): Not applicable.

· Ignition temperature: 255 °C

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:
  Lower: Not determined.
### 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** Based on available data, the classification criteria are not met.

<table>
<thead>
<tr>
<th>LD/LC50 values relevant for classification:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ATE (Acute Toxicity Estimates)</strong></td>
</tr>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>LD50</td>
</tr>
<tr>
<td>LC50/4 h</td>
</tr>
<tr>
<td>Inhalative</td>
</tr>
<tr>
<td>LC50/4 h</td>
</tr>
<tr>
<td>LC50 (Daphnia magna) (static)</td>
</tr>
</tbody>
</table>

#### 1314-13-2 Zinc Oxide

<table>
<thead>
<tr>
<th>Oral</th>
<th>LD50</th>
<th>7,950 mg/kg (mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish</td>
<td></td>
<td>&gt;320 mg/l (Fish)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inhalative</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/4 h</td>
</tr>
</tbody>
</table>

#### 112926-00-8 Synthetic Amorphous Silica

<table>
<thead>
<tr>
<th>Oral</th>
<th>LD50</th>
<th>&gt;5,000 mg/kg (rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>&gt;5,000 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>
Trade name: UltraTemp® REZ Catalyst - Regular and Fast

<table>
<thead>
<tr>
<th></th>
<th>Inhalative</th>
<th>109-16-0 Triethylene Glycol Dimethacrylate</th>
<th>99-97-8 Dimethyl-p-toluidine</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50/4 h</td>
<td>&gt;0.69 mg/l (rat)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>&gt;5,000 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LC50 Fish</td>
<td>16.4 mg/l (Fish) (Toxicity to fish)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>&gt;2,000 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
<td>1.4 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

· Primary irritant effect:
  · Skin corrosion/irritation Based on available data, the classification criteria are not met.
  · Serious eye damage/irritation Based on available data, the classification criteria are not met.
  · Respiratory or skin sensitisation
    May cause an allergic skin reaction.

· CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  · Germ cell mutagenicity Based on available data, the classification criteria are not met.
  · Carcinogenicity Based on available data, the classification criteria are not met.
  · Reproductive toxicity Based on available data, the classification criteria are not met.
  · STOT-single exposure Based on available data, the classification criteria are not met.
  · STOT-repeated exposure Based on available data, the classification criteria are not met.

· Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

· Toxicity

1314-13-2 Zinc Oxide

| EC50         | 2.066 mg/kg (Fish) |

109-16-0 Triethylene Glycol Dimethacrylate

| Aqua toxicity | 32 mg/l (daphnia) (No Observed Effect Concentration) |
| EC50         | >100 mg/l (Algae) (Toxicity to algae) |

· Persistence and degradability No further relevant information available.
· Behaviour in environmental systems:
  · Bioaccumulative potential No further relevant information available.
  · Mobility in soil No further relevant information available.
· Ecotoxicical effects:
  · Remark: Very toxic for fish
· Additional ecological information:
  · General notes:
    Water hazard class 2 (German Regulation) (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.
    Also poisonous for fish and plankton in water bodies.
    Very toxic for aquatic organisms
· Results of PBT and vPvB assessment
  · PBT: Not applicable.
  · vPvB: Not applicable.
13 Disposal considerations

- Waste treatment methods
- Recommendation
  Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- European waste catalogue
  | HP 13 | Sensitising |
  | HP 14 | Ecotoxic |

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - ADR, ADN, IMDG, IATA not regulated

- UN proper shipping name
  - ADR, ADN, IMDG, IATA not regulated

- Transport hazard class(es)
  - ADR, ADN, IMDG, IATA not regulated
  - Class not regulated

- Packing group
  - ADR, IMDG, IATA not regulated

- Environmental hazards: Not applicable.

- Special precautions for user Not applicable.
- Stowage Category E

- Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

- UN "Model Regulation": not regulated

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: E1: Hazardous to the Aquatic Environment

- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 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**
  - H301 Toxic if swallowed.
  - H311 Toxic in contact with skin.
  - H317 May cause an allergic skin reaction.
  - H331 Toxic if inhaled.
  - H373 Toxic if inhaled.
  - H400 Very toxic to aquatic life.
  - H410 Very toxic to aquatic life with long lasting effects.
  - H412 Harmful to aquatic life with long lasting effects.

- **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
  - Acute Tox. 3: Acute toxicity – Category 3
  - Skin Sens. 1: Skin sensitisation – Category 1
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
  - Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3