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

- **Product identifier**
  - **Trade name:** UltraTemp REZ Base
  - **Article number:** 15092
  - **Index number:** SDS 201-001.05
  - **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:** Customer Service
  - **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**
    ![GHS07]

    Skin Irrit. 2  H315  Causes skin irritation.
    Eye Irrit. 2  H319  Causes serious eye irritation.
    Aquatic Chronic 3  H412  Harmful to aquatic life with long lasting effects.

- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    The product is classified and labelled according to the CLP regulation.
  - **Hazard pictograms**
    ![GHS07]

- **Signal word** Warning
· **Hazard statements**
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
  H412 Harmful 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.
  P273 Avoid release to the environment.
  P280 Wear protective gloves / eye protection / face protection.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P332+P313 If skin irritation occurs: Get medical advice/attention.
  P337+P313 If eye irritation persists: Get medical advice/attention.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information**: Contains Benzoyl Peroxide. May produce an allergic reaction.

· **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.

#### Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Chemical name</th>
<th>H315</th>
<th>H319</th>
<th>H412</th>
</tr>
</thead>
<tbody>
<tr>
<td>27813-02-1</td>
<td>248-666-3</td>
<td>Hydroxypropyl methacrylate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Ethyl Alcohol</td>
<td></td>
<td></td>
<td>≤2.5%</td>
</tr>
<tr>
<td>94-36-0</td>
<td>202-327-6</td>
<td>Benzoyl Peroxide</td>
<td></td>
<td></td>
<td>≤2.5%</td>
</tr>
<tr>
<td>14808-60-7</td>
<td>238-878-4</td>
<td>Silica Glass</td>
<td></td>
<td></td>
<td>≤2.5%</td>
</tr>
</tbody>
</table>

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

· **Information for doctor**

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

- **Extinguishing media**
- **Suitable extinguishing agents:**
  - Water spray, fog, or mist, foam, dry chemical, carbon dioxide
  - 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.
- **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.
  - Keep container tightly sealed.
- **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:**
    - 64-17-5 Ethyl Alcohol
      - WEL Long-term value: 1920 mg/m³, 1000 ppm
    - **Additional information:** The lists valid during the making 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.
  Avoid contact with the eyes and skin.
· 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:

Tightly sealed goggles

· Body protection: Protective work clothing

---

9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information</td>
</tr>
<tr>
<td>Appearance:</td>
</tr>
<tr>
<td>· Form: Gel</td>
</tr>
<tr>
<td>· Colour: Blue</td>
</tr>
<tr>
<td>· Odour: Almond</td>
</tr>
<tr>
<td>· Odour threshold: Not determined.</td>
</tr>
<tr>
<td>· pH-value: Not applicable (non-aqueous)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change in condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Melting point/freezing point: Undetermined.</td>
</tr>
<tr>
<td>· Initial boiling point and boiling range: Undetermined.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flash point:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flammability (solid, gas):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Decomposition temperature:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not determined.</td>
</tr>
</tbody>
</table>
Trade name: UltraTemp® REZ Base

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-ignition temperature</td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Product does not present an explosion hazard.</td>
</tr>
<tr>
<td>Lower limits</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Upper limits</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Density at 20 °C</td>
<td>0.985 g/cm³</td>
</tr>
<tr>
<td>Relative density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Solubility in / Miscibility with water</td>
<td>Not miscible or difficult to mix.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not determined.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Dynamic: Not determined.</td>
</tr>
<tr>
<td></td>
<td>Kinematic: Not determined.</td>
</tr>
<tr>
<td>Solvent content</td>
<td>Water: &lt; 1 %</td>
</tr>
<tr>
<td></td>
<td>VOC (EC): 0.00 %</td>
</tr>
<tr>
<td>Other information</td>
<td>No further relevant information available.</td>
</tr>
</tbody>
</table>

## 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.
- LD/LC50 values relevant for classification:

### ATE (Acute Toxicity Estimates)

<table>
<thead>
<tr>
<th>Inhalation</th>
<th>LC50/4 h</th>
<th>1.99 mg/l (rat)</th>
</tr>
</thead>
</table>

### 64-17-5 Ethyl Alcohol

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50 Fish</th>
<th>LC50/4 h</th>
<th>LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>5,600 mg/kg (Guinea pig)</td>
<td>&gt;10,000 mg/l (Fish)</td>
<td>39 mg/l (mouse)</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>3,400 mg/kg (mouse)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>7,060 mg/kg (rat)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Trade name: UltraTemp® REZ Base

<table>
<thead>
<tr>
<th>94-36-0 Benzoyl Peroxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>LC50</td>
</tr>
<tr>
<td>Inhalative</td>
</tr>
<tr>
<td>20,000 mg/l (rat)</td>
</tr>
</tbody>
</table>

- **Primary irritant effect:**
  - **Skin corrosion/irritation**
    Causes skin irritation.
  - **Serious eye damage/irritation**
    Causes serious eye irritation.
  - **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
  - **CMR effects** (carcinogenicity, 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**

  - **Aquatic toxicity:**
    - 64-17-5 Ethyl Alcohol
      - Algae Toxicity 1,000 mg/l (Algae)
    - 94-36-0 Benzoyl Peroxide
      - Algae Toxicity 0.0711 mg/l (Algae) (Toxicity to algae)
      - 0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)

  - **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.
  - **Ecotoxicological effects:**
    - **Remark:** Harmful to fish
  - **Additional ecological information:**
  - **General notes:**
    - Generally not hazardous for water
    - Harmful to aquatic organisms
  - **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**
    Must not be disposed together with household garbage. Do not allow product to reach sewage system.
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 14.06.2018
Revision: 04.04.2018

Trade name: UltraTemp® REZ Base

- European waste catalogue
  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
  B

- 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.
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 40
  - 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
  H225 Highly flammable liquid and vapour.
  H241 Heating may cause a fire or explosion.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.
  H332 Harmful if inhaled.
  H410 Very toxic to aquatic life with long lasting effects.
Trade name: UltraTemp® REZ Base

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
Flam. Liq. 2: Flammable liquids – Category 2
Org. Perox. B: Organic peroxides – Type B
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – 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