Safety data sheet
according to 1907/2006/EC, Article 31

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

· Product identifier
· Trade name: UltraTemp™ REZ Base
· Article number: 15092
· Index number: SDS 201-001.06
· 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@utradent.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

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 Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

· Hazard pictograms GHS07
· Signal word Warning
· Hazard statements
  H315 Causes skin irritation.
  H319 Causes serious eye irritation.
Trade name: UltraTemp™ REZ Base

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.
  P264 Wash thoroughly after handling.
  P273 Avoid release to the environment.
  P280 Wear protective gloves / eye protection / face protection.
  P302+P352 IF ON SKIN: Wash with plenty of water.
  P321 Specific treatment (see on this label).
  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.
  P362+P364 Take off contaminated clothing and wash it before reuse.
  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:
  - CAS: 27813-02-1 Hydroxypropyl Methacrylate
    - EINECS: 248-666-3
    - Skin Irrit. 2, H315; Eye Irrit. 2, H319
    - >2.5-≤10%
  - CAS: 64-17-5 Ethyl Alcohol
    - EINECS: 200-578-6
    - Flam. Liq. 2, H225
    - ≤2.5%
  - CAS: 94-36-0 Benzoyl Peroxide
    - EINECS: 202-327-0
    - Org. Perox. B, H241; Aquatic Chronic 1, H410; Eye Irrit. 2, H319; Skin Sens. 1, H317
    - ≤2.5%
  - CAS: 14808-60-7 Silica Glass
    - EINECS: 238-878-4
    - Acute Tox. 4, H332; Skin Irrit. 2, H315
    - ≤2.5%

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

4 First aid measures

- Description of first aid measures
- General information: Immediately remove any clothing soiled by the product.
- After inhalation:
  This product is a viscous gel, therefore chance of inhalation is extremely low.
  Seek medical treatment in case of complaints.
- After skin contact:
  Immediately wash with water and soap and rinse thoroughly.
  If skin irritation continues, consult a doctor.
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: Wear fully protective suit.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures
  Wear protective equipment. Keep unprotected persons away.
· Environmental precautions:
  Do not allow product to reach sewage system or any water course.
  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).
  Dispose contaminated material as waste according to item 13.
· 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.
  · 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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td>WEL (Great Britain) Long-term value: 1920 mg/m³, 1000 ppm</td>
</tr>
</tbody>
</table>

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

Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:
- Form: Gel
- Colour: Blue
- Odour: Almond
- Odour threshold: Not determined.

pH-value: Not applicable (non-aqueous)

Change in condition
- Melting point/freezing point: Undetermined.
Trade name: UltraTemp™ REZ Base

### Initial boiling point and boiling range:
- Undetermined.

### Flash point:
- Not applicable.

### Flammability (solid, gas):
- Not applicable.

### 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.
- Upper: Not determined.

### Vapour pressure:
- Not determined.

### Density at 20 °C:
- 0.985 g/cm³

### Relative density:
- Not determined.

### Vapour density:
- Not determined.

### Evaporation rate:
- Not determined.

### Solubility in / Miscibility with water:
- Not miscible or difficult to mix.

### Partition coefficient: n-octanol/water:
- Not determined.

### Viscosity:
- Dynamic: Not determined.
- Kinematic: Not determined.

### Solvent content:
- Water: <1 %
- VOC (EC): <2%

### Other information
- No further relevant information available.

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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.

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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)
- Inhalative: LC50/4 h 1.99 mg/l
Trade name: UltraTemp™ REZ Base

<table>
<thead>
<tr>
<th>Compound</th>
<th>Oral LD50</th>
<th>Oral LC50/Fish</th>
<th>Inhalative LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td>5,600 mg/kg (Guinea pig)</td>
<td>3,400 mg/kg (mouse)</td>
<td>7,060 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>64-17-5 Ethyl Alcohol</td>
<td>&gt;10,000 mg/l (Fish)</td>
<td>39 mg/l (mouse)</td>
</tr>
<tr>
<td></td>
<td>64-17-5 Ethyl Alcohol</td>
<td>20,000 mg/l (rat)</td>
<td></td>
</tr>
<tr>
<td>94-36-0 Benzoyl Peroxide</td>
<td>5,000 mg/kg (rat)</td>
<td>0.0602 mg/l (Fish) (Toxicity to fish)</td>
<td>24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)</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:**
    - Not hazardous for water.
    - Harmful to 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
  · HPT4 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
  · Class not regulated

· Packing group
  · ADR, IMDG, IATA not regulated

· Environmental hazards:
  · Not applicable.

· Special precautions for user
  · Not applicable.

· 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

· 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.

(Contd. of page 6)
Trade name: UltraTemp™ REZ Base

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.

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 - inhalation – 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