UltraTemp®, Part 2 of 2 (Base)

**SECTION 1: Identification of the substance/preparation and of the company/undertaking**

1.1. **Product identifier**
- **Product code**: UB/81242
- **Product name**: UltraTemp®, Part 2 of 2 (Base)
- **Product description**: Non-Eugenol Temporary Luting/Filling Material

1.2. **Relevant identified uses of the substance or mixture and uses advised against**
- **Relevant identified uses**: Professional Dental Temporary Cement

1.3. **Details of the supplier of the safety data sheet**
- **Manufacturer**: Ultradent Products, Inc.
  - 505 W. Ultradent Drive (10200 South)
  - South Jordan, UT 84095
- **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

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 Regulation (EC) No 1272/2008 [CLP]**:
  - **Environmental**: Chronic Hazards to the Aquatic Environment, Category 1

2.2. **Label elements**
- **Classification according to Regulation (EC) No 1272/2008 [CLP]**
- **Hazard pictogram(s)**: ![Environment]
- **Signal Word**: WARNING
- **Hazard statement(s)**: H410: Very toxic to aquatic life with long lasting effects.
- **Precautionary statement(s)**
  - **Prevention**: P273: Avoid release to the environment.
  - **Response**: P391: Collect spillage.

2.3. **Other hazards**
Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

### SECTION 3: Composition / information on ingredients

#### 3.1. Substances
Not Applicable

#### 3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc Oxide</td>
<td>1314-13-2</td>
<td>215-222-5</td>
<td>≤ 35</td>
<td>Aquatic Acute,Cat. 1; H410; H400</td>
</tr>
<tr>
<td>Silica</td>
<td>112926-00-8</td>
<td>- -</td>
<td>≤ 20</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

**Following eyes**: Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

**Following skin**: Wash with soap and water.

**Following ingestion**: If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation**: No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

- **Eyes**: May cause mild irritation.
- **Skin**: May cause slight irritation.
- **Ingestion**: May be harmful if swallowed in large quantities.
- **Inhalation**: None expected for this product.

#### 4.3. Indication of any immediate medical attention and special treatment needed

**Notes to physician**: NAP

### SECTION 5: Fire fighting measures

#### 5.1. Extinguishing media

**Extinguishing media**: Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

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

**Hazardous combustion products**: Not Established

#### 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.
UltraTemp®, Part 2 of 2 (Base)

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 with cloth, soap and 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: NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling: Use suitable protective equipment.

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 Temporary Cement

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Zinc Oxide (Respirable Fraction) CAS: 1314-13-2

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Construction Industry</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Maritime</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>2mg/m³ TWA; 10mg/m³ STEL - Respirable fraction</td>
</tr>
</tbody>
</table>

Zinc Oxide (Total Dust) CAS: 1314-13-2

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Construction Industry</td>
<td>15mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Maritime</td>
<td>5mg/m³</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>5mg/m³ TWA; 15mg/m³ Ceiling</td>
</tr>
</tbody>
</table>
Zinc Oxide Fume CAS:1314-13-2

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Construction Industry</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>OSHA PEL Shipyard Employment</td>
<td>5mg/m³ TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>2mg/m³ TWA 10mg/m³ STEL</td>
</tr>
<tr>
<td>CAL/OSHA PELs</td>
<td>5mg/m³ TWA 10mg/m³ STEL</td>
</tr>
</tbody>
</table>

Silica CAS:112926-00-8

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>20 mppcf, 80mg/m³ %SiO2 TWA</td>
</tr>
<tr>
<td>OSHA PEL Maritime</td>
<td>20 mppcf TWA</td>
</tr>
<tr>
<td>OSHA PEL Construction Industry</td>
<td>20 mppcf TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>6mg/m³ TWA</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

Eye/face protection : Wear eye protection.
Skin protection : Wear suitable protective clothing and gloves.
Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Paste
Colour : Beige
Odour : NAP
pH : NAP (non-aqueous)
Specific gravity : 1.8 - 1.9

9.2. Other information

Additional information : No further relevant information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable
UltraTemp®, Part 2 of 2 (Base)

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 : None known.

10.5. Incompatible materials
Incompatible materials : None known.

10.6. Hazardous decomposition products
Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute
Dermal LD₅₀ : 5000 mg/kg Rabbit
Notes : 63% of the mixture consists of components of unknown toxicity (dermal)
Oral LD₅₀ : > 1400 mg/kg Rat/Mouse
Notes : There are no components of unknown toxicity (oral).
Inhalation LC₅₀ : > 16 mg/L/4H Mouse/Rat
Notes : There are no components of unknown toxicity (inhalation).
Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity
Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability
Persistence and degradability : Not classified

12.3. Bioaccumulative potential
Bioaccumulative potential : Not classified

12.4. Mobility in soil
Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment
Results of PBT and vPvB assessment : Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects
Environmental data : Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
UltraTemp®, Part 2 of 2 (Base)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

SECTION 14: Transport information

14.1. UN number
UN number : NAP

14.2. UN proper shipping name
UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)
Hazard classification : NAP

14.4. Packing group
Packing group : NAP

14.5. Environmental hazards
Marine pollutant #1 : NAP

14.6. Special precautions for user
ADR - road : NAP
RID - rail : NAP
IMDG - sea : NAP
IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
General information : Substances of very high concern (SVHC) according to REACH, Article 57:
Contains no SVHC substances.

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment
Chemical safety assessment : See Section 11
Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text) : Aquatic Acute, Cat. 1: Acute Hazards to the Aquatic Environment, Category 1
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

UltraTemp®, Part 2 of 2 (Base)

Prepared by : Anu Kattoju

Revision summary
: This SDS replaces the 09/23/2016 SDS. Revised: Section 1: MSDS No. Section 4: NOTES TO PHYSICIAN. Section 6: PERSONAL PROTECTIVE EQUIPMENT - EYES AND FACE. Section 9: COMMENTS, PERCENT VOLATILE. Section 11: ACUTE, GENERAL COMMENTS. Section 15: GENERAL COMMENTS, RoHS.

General statements
: NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
AMU = Atomic Mass Unit

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.