

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 12/14/2006  
SDS No : 72-001.11  
Date Revised : 03/22/2017  
Revision No : 9

## 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]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

##### 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.

##### Disposal

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

#### 2.3. Other hazards

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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

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

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 (CO<sub>2</sub>)

#### 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.

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**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

Control Parameters	Exposure Limits
OSHA PEL General Industry	5mg/m <sup>3</sup> TWA
OSHA PEL Construction Industry	5mg/m <sup>3</sup> TWA
OSHA PEL Maritime	5mg/m <sup>3</sup> TWA
ACGIH TLV	2mg/m <sup>3</sup> TWA; 10mg/m <sup>3</sup> STEL - Respirable fraction

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

OSHA PEL General Industry	5mg/m <sup>3</sup> TWA
OSHA PEL Construction Industry	15mg/m <sup>3</sup> TWA
OSHA PEL Maritime	5mg/m <sup>3</sup>
NIOSH REL	5mg/m <sup>3</sup> TWA; 15mg/m <sup>3</sup> Ceiling

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Zinc Oxide Fume CAS:1314-13-2

OSHA PEL General Industry	5mg/m <sup>3</sup> TWA
OSHA PEL Construction Industry	5mg/m <sup>3</sup> TWA
OSHA PEL Shipyard Employment	5mg/m <sup>3</sup> TWA
NIOSH REL	2mg/mg/m <sup>3</sup> TWA 10mg/m <sup>3</sup> STEL
CAL/OSHA PELs	5mg/m <sup>3</sup> TWA 10mg/m <sup>3</sup> STEL

Silica CAS:112926-00-8

Control Parameters	Exposure Limits
OSHA PEL General Industry	20 mppcf, 80mg/m <sup>3</sup> /%SiO <sub>2</sub> TWA
OSHA PEL Maritime	20 mppcf TWA
OSHA PEL Construction Industry	20 mppcf TWA
NIOSH REL	6mg/m <sup>3</sup> TWA

## 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

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**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 LD<sub>50</sub>** : 5000 mg/kg Rabbit

**Notes** : 63% of the mixture consists of components of unknown toxicity (dermal)

**Oral LD<sub>50</sub>** : > 1400 mg/kg Rat/Mouse

**Notes** : There are no components of unknown toxicity (oral).

**Inhalation LC<sub>50</sub>** : > 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.

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**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**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.

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**Revision summary** : This SDS replaces the 09/23/2016 SDS. Revised: **Section 1:** MSDS No. **Section 4:** NOTES TO PHYSICIAN. **Section 6:** . **Section 8:** 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.