

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/09/2006

SDS No : 22-001.8

Date Revised : 05/05/2015

Revision No : 8

## UltraTemp® , Part 1 of 2 (Catalyst)

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

#### 1.1. Product identifier

**Product code** : UK/81247  
**Product name** : UltraTemp® , Part 1 of 2 (Catalyst)  
**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 Luting/Filling Material

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

##### Distributor

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 Directive 1999/45/EC

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

**Danger symbols** : Xi

**R phrases** : R36/38

##### Classification according to Regulation (EC) No 1272/2008 [CLP]

**Health** : Eye Irritation  
 Skin Irritation, Category 2

#### 2.2. Label elements

##### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/38: Irritating to eyes and skin.

##### Classification according to Regulation (EC) No 1272/2008 [CLP]

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Hazard pictogram(s)

:



Exclamation  
mark

Signal Word

: WARNING

Hazard statement(s)

: H319: Causes serious eye irritation.  
H315: Causes skin irritation.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response

: P305: IF IN EYES:  
P351: Rinse cautiously with water for several minutes.  
P337+P313: If eye irritation persists: Get medical advice/attention.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.

Storage

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

### 2.3. Other hazards

Immediate concerns

: None

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Benzoic Acid	65-85-0	200-618-2	≤ 15	Xi; R36/37/38	Skin Irr.,Cat. 2; Ser. Eye Dmg.,Cat. 1; H315; H318
4-Methoxyphenol	150-76-5	205-769-8	≤ 1	Xi; R36	Eye Irr.,Cat. 2; Skin Sens.,Cat. 1; Acute Tox. (O),Cat. 4; H302; H317;

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					H319
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For full text of H-statements and R-phrases: 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. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

- Eyes** : May cause mild irritation.
- Skin** : May cause slight irritation.
- Ingestion** : None expected for this product.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Not Applicable

### SECTION 5: Fire fighting measures

#### 5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

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

- General hazard** : Not Determined
- Hazardous combustion products** : None known.
- Explosion hazards** : None known.
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

#### 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.
- Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

### SECTION 6: Accidental release measures

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### 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** : Not Applicable

## 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 Luting/Filling Material

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

**Control parameters** : Not Determined

### 8.2. Exposure controls

**Eye/face protection** : Wear eye protection

**Skin protection** : Wear suitable protective clothing and gloves.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Physical state** : Gel

**Colour** : Clear

**Odour** : Pungent, typical acrylic acid odor.

### 9.2. Other information

**Percent volatile** : Not Determined

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

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**Reactivity** : Stable

### 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** : Not Determined

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute

**Notes** : 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.

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

### 12.2. Persistence and degradability

**Persistence and degradability** : Not Determined

### 12.3. Bioaccumulative potential

**Bioaccumulative potential** : Not Determined

### 12.4. Mobility in soil

**Mobility in soil** : Not Determined

### 12.5. Results of PBT and vPvB assessment

**Results of PBT and vPvB assessment** : Not Determined

### 12.6. Other adverse effects

**Environmental data** : Not Established

## SECTION 13: Disposal considerations

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### 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** : N/A

### 14.2. UN proper shipping name

**UN proper shipping name** : Not Dangerous Goods

### 14.3. Transport hazard class(es)

**Primary hazard class/division** : N/A

### 14.4. Packing group

**Packing group** : N/A

### 14.5. Environmental hazards

**Marine pollutant #1** : N/A

### 14.6. Special precautions for user

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

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

**Transport in bulk** : Not Dangerous Goods

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

### 15.2. Chemical safety assessment

**Chemical safety assessment** : See Section 11

## SECTION 16: Other information

**Relevant R-phrases and/or H-statements (number and full text)** : R36/37/38: Irritating to eyes, respiratory system and skin.  
R36: Irritating to eyes.  
Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Eye Irr., Cat. 2: Eye Irritation, Category 2  
Ser. Eye Dmg., Cat. 1: Serious Eye Damage, Category 1  
Skin Irr., Cat. 2: Skin Irritation, Category 2  
Skin Sens., Cat. 1: Skin Sensitization, Category 1  
H302: Harmful if swallowed.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.

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H318: Causes serious eye damage.

H319: Causes serious eye irritation.

### Prepared by

: Anu Kattoju

### Revision summary

: This SDS replaces the 08/07/2014 SDS. Revised: **Section 1:**  
**Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE ( ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat) ACUTE. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID) ( PROPER SHIPPING NAME ), VESSEL (IMO/IMDG) - SPECIAL PROVISIONS ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

### General statements

: N/A= Not Applicable

### 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.