

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/14/2006

SDS No : 72-001.6

Date Revised : 5/28/2014

Revision No : 5

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 : Dual component temporary cement consisting of a base and catalyst.

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. 10200 S.
 South Jordan, UT 84095

Distributor

UP Dental GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: info@updental.de
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**

Danger symbols : N
R phrases : R50/53

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : N



Dangerous
 for the
 environment

R&S statement(s) : R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

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ULTRADENT
 PRODUCTS, INC.

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UltraTemp® ,Part 2 of 2 (Base)

Hazard pictogram(s)

:



Environment

Hazard statement(s)

: H411: Toxic to aquatic life with long lasting effects.

2.3. Other hazards

Immediate concerns

: No adverse human effects

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
Zinc Oxide	1314-13-2	215-222-5	<= 35	N; R50/53

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, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

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

: May be harmful if swallowed.

Inhalation

: None expected for this product.

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

Notes to physician

: N/A

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UltraTemp® ,Part 2 of 2 (Base)**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****Hazardous combustion products** : Not Determined**Explosion hazards** : Not Determined**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(CO₂)**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** : 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 Cement**SECTION 8: Exposure controls / personal protection**

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UltraTemp® ,Part 2 of 2 (Base)

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : S36/37: 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 : Oil

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable : Yes

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : No

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 : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

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12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : 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 : R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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 : N/A

14.2. UN proper shipping name

UN proper shipping name : Not classified

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 : N/A

RID - rail : N/A

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IMDG - sea : N/A

IATA - air : N/A

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

Transport in bulk : N/A

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 : Not Determined

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R36: Irritating to eyes.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 1/22/2014 SDS. Revised: **Section 1:** GENERAL USE. **Section 4:** NOTES TO PHYSICIAN. **Section 7:** SHELF LIFE, STORAGE, . **Section 16:** GENERAL STATEMENTS.

General statements : NA = Not Applicable

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.

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Date Issued : 2/9/2006

SDS No : 22-001.7

Date Revised : 8/7/2014

Revision No : 7

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 : Clear gel used to accelerate UltraTemp luting and 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**

Danger symbols : Xi
R phrases : R36/38

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]

Hazard pictogram(s) :



Exclamation mark

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 Date Revised : 8/7/2014
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UltraTemp® Part 1 of 2 (Catalyst)

Signal Word : WARNING
Hazard statement(s) : H320: Causes eye irritation.
 H315: Causes skin irritation.

2.3. Other hazards

Immediate concerns : No other adverse human effects.

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
Benzoic Acid	65-85-0	200-618-2	<= 15	Xi; R36/37/38
Phenol, 4-methoxy-	150-76-5	205-769-8	<= 1	Xi; R36

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

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Date Issued : 2/9/2006

SDS No : 22-001.7

Date Revised : 8/7/2014

Revision No : 7

UltraTemp® Part 1 of 2 (Catalyst)**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(CO₂)**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** : 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**

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UltraTemp® Part 1 of 2 (Catalyst)

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : S36/37: 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

Stable : Yes

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions : None known.

Hazardous polymerization : No

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

Dermal LD₅₀ : Not Determined

Oral LD₅₀ : Not Determined

Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

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Date Issued : 2/9/2006

SDS No : 22-001.7

Date Revised : 8/7/2014

Revision No : 7

UltraTemp® Part 1 of 2 (Catalyst)**12.1. Toxicity**

Aquatic toxicity (acute)	: Do not allow to enter sewers or drains that may lead to waterways.
96-hour LC₅₀	: Not Determined
48-hour EC₅₀	: Not Determined
96-hour EC₅₀	: Not Determined

12.2. Persistence and degradability

Persistence and degradability	: Not Determined
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12.3. Bioaccumulative potential

Bioaccumulative potential	: Not Determined
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12.4. Mobility in soil

Mobility in soil	: Not Determined
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	: Not Determined
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12.6. Other adverse effects

Environmental data	: Not Established
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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)
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SECTION 14: Transport information**14.1. UN number**

UN number	: N/A
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14.2. UN proper shipping name

UN proper shipping name	: Not classified
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14.3. Transport hazard class(es)

Primary hazard class/division	: N/A
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14.4. Packing group

Packing group	: N/A
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14.5. Environmental hazards

Marine pollutant #1	: N/A
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14.6. Special precautions for user

ADR - road	: N/A
RID - rail	: N/A
IMDG - sea	: N/A

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UltraTemp® Part 1 of 2 (Catalyst)

IATA - air : N/A

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

Transport in bulk : N/A

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 : Not Determined

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.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 5/13/2014 SDS. Revised: **Section 1:**
 . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS.

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.