

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 02/09/2006
SDS No : 22-001.10
Date Revised : 05/25/2016
Revision No : 10

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 : Skin Irritation, Category 2
Eye Irritation, Category 2
Acute Toxicity (Inhalation), Category 3

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi



Irritant

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

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word : DANGER

Hazard statement(s) : H319: Causes serious eye irritation.
H315: Causes skin irritation.
H335: May cause respiratory 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.
P301: IF SWALLOWED:
P331: Do NOT induce vomiting.
P330: Rinse mouth.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion: The substance does not fulfill the PBT and vPvB criteria for screening assessment. There is not 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 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; 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; H319

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

SECTION 4: First aid measures

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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 Don't induce vomiting. Rinse mouth and seek medical advice if necessary.
Following inhalation	: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

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	: May be harmful if inhaled.

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

Notes to physician	: Not Applicable
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SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media	: Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO2)
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5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	: None known.
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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.
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6.2. Environmental precautions

Water spill	: Do not allow to enter sewers or drains that may lead to waterways.
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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
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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling	: Use suitable protective equipment.
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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 : 4-Methoxyphenol CAS: 150-76-5

Control Parameters	Exposure Limits
8 hr TWA	5mg/m ³
NIOSH REL 10-hr TWA	5mg/m ³
ACGIH TLV	5mg/m ³
Excursion Limit Recommendation	May exceed 3x the TLV-TWA for no > than 30 minutes during work day, and under no circumstances should they exceed 5x the TLV-TWA

Silicon Dioxide CAS: 7631-86-9

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

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

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

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Percent volatile : Not Available

SECTION 10: Stability and reactivity

10.1. Reactivity

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 : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 4000 mg/kg(rabbit/rat)

Notes : 92% of the mixture consists of components of unknown toxicity(dermal)

Oral LD₅₀ : > 3500 mg/kg (rat)

Notes : 92% of the mixture consists of components of unknown toxicity(oral)

Inhalation LC₅₀ : > 7 mg/L/4H rat

Notes : 93% of the mixture consists of components of unknown toxicity(inhalation)

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.

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

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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.

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 : 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

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

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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 DMG., Cat. 1: Eye Damage, Category 1
Eye Irr., Cat. 2: Eye Irritation, Category 2
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.
H318: Causes serious eye damage.
H319: Causes serious eye irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 09/24/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXTINGUISHING MEDIA, FIRE FIGHTING EQUIPMENT. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY. **Section 9:** PERCENT VOLATILE. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat)). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 UN number, Primary hazard class/division, Packing group. **Section 15:** COMMENTS. **Section 16:** GENERAL STATEMENTS.

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

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.