

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/14/2006

SDS No : 72-001.10

Date Revised : 09/23/2016

Revision No : 8

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. 10200 S.
 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 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 : N

R phrases : R50/53

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

Environmental : Acute Hazards to the Aquatic Environment, Category 1

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

Hazard pictogram(s) : N



Dangerous
for the
environment

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

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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 :

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. (EC1975L0442-20/11/2003)

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

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Zinc Oxide	1314-13-2	215-222-5	≤ 35	N; R50/53	Aquatic Acute, Cat. 1; H410; H400
Silica	112926-00-8	- -	≤ 20	R36/37	Not classified

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.

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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	: 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(CO ₂)
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5.2. Special hazards arising from the substance or mixture

Hazardous combustion products	: Not Established
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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.
Storage	: See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life	: See product labeling
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7.3. Specific end use(s)

Specific end use(s)	: Professional Dental Temporary Cement
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

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Control parameters

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

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

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

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

Zinc Oxide Fume CAS:1314-13-2

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

Silica CAS:112926-00-8

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 safety glasses with side shields

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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

Percent volatile : Not Determined

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 : 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).

Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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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.

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

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Transport in bulk : NAP

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****General Information** : 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 R-phrases and/or H-statements (number and full text) : R36/37: Irritating to eyes and respiratory system.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
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.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 05/31/2016 SDS. Revised: **Section 1:** MSDS
No. **Section 9:** ODOR, pH, SPECIFIC GRAVITY. **Section 14:** ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air.

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.