

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/15/2008

SDS No : 202-001.4

Date Revised : 05/04/2015

Revision No : 3

UltraTemp® REZ Regular & UltraTemp® REZ Fast - Catalyst

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

1.1. Product identifier

Product code : UO/15093, UP/15094
Product name : UltraTemp® REZ Regular & UltraTemp® REZ Fast - Catalyst
Product description : Accelerator for luting and filling material

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Dental Non-Eugenol Temporary Luting & Filling Agent

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,N

R phrases : R36/38,R43,R50/53

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

Health : Skin Sensitization
 Eye Irritation
 Skin Irritation

Environmental : Chronic Hazards to the Aquatic Environment, Category 1
 Aquatic Toxicity, Acute Category 1

2.2. Label elements

Classification according to Directive 1999/45/EC

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Hazard pictogram(s)

:

Xi

N



Irritant



Dangerous
for the
environment

R&S statement(s)

:

R36/38: Irritating to eyes and skin.

R43: May cause sensitization by skin contact.

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]

Hazard pictogram(s)

:



Environment



Exclamation
mark

Signal Word

:

WARNING

Hazard statement(s)

:

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

H319: Causes serious eye 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

Physical hazards

:

Harmful to aquatic life with long lasting effects.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Bis GMA	1565-94-2	216-367-7	≤ 35	Xi; R36/37/38; R22	H302; H315; H317; H318; H335; H412
Triethylene glycol dimethacrylate	109-16-0	203-652-6	≤ 15	Xi; R43	H317
Zinc Oxide	1314-13-2	215-222-5	≤ 30	N; R50/53	Aquatic Chronic, Cat. 1; Aquatic Tox., ACUTE CAT. 1; H410; H400

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.

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

- Eyes** : Causes eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : 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

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** : None known.

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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(CO ₂)

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 Non-Eugenol Temporary Luting & Filling Agent
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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters	: Not Determined
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8.2. Exposure controls

Eye/face protection	: Wear eye protection
Skin protection	: Wear suitable protective clothing and gloves.

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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 : Opaque beige
Odour : Acrylic

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 : Not Determined

10.5. Incompatible materials

Incompatible materials : Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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 LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

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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 : 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 Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : 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

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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) : R22: Harmful if swallowed.
R36/37/38: Irritating to eyes, respiratory system and skin.
R43: May cause sensitization by skin contact.
R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Aquatic Chronic, Cat. 1: Chronic Hazards to the Aquatic Environment, Category 1
Aquatic Tox., ACUTE CAT. 1: Aquatic Toxicity, Acute Category 1
H302: Harmful if swallowed.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H335: May cause respiratory irritation.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/11/2014 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 12:** ENVIRONMENTAL DATA. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1. **Section 15:** SECTION 15: Regulatory information.

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.