

## Safety Data Sheet

according to WHS Regulations

Printing date 25.03.2024

Revision: 25.03.2024

### 1 Identification

- **Product identifier**
- **Trade name:** *UltraTemp™ REZ II - Base*
- **Article number:** *SDS 440-001.02R01, 1007603*
- **Relevant identified uses of the substance or mixture and uses advised against**  
*Professional dental luting & filling agent*
- **Application of the substance / the mixture** *Professional dental luting & filling agent*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*Ultradent Products, Inc.  
505 W. Ultradent Drive (10200 S)  
South Jordan, UT 84095-3942  
USA  
onlineordersupport@ultradent.com*
- Ultradent Australia Pty Ltd.  
Level 22/2 Market Street  
Sydney NSW 2000  
Australia  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929*
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**  
*CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887*

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**



<i>Skin Irrit. 2</i>	<i>H315 Causes skin irritation.</i>
<i>Serious eye damage/irritation – Category 2A</i>	<i>H319 Causes serious eye irritation.</i>
<i>Skin Sens. 1</i>	<i>H317 May cause an allergic skin reaction.</i>

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS07*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**  
*Hydroxypropyl Methacrylate*
- **Hazard statements**  
*H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H317 May cause an allergic skin reaction.*

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### · Precautionary statements

- P101 If medical advice is needed, have product container or label at hand.  
 P102 Keep out of reach of children.  
 P103 Read label before use.  
 P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves / eye protection / face protection.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
 P337+P313 If eye irritation persists: Get medical advice/attention.  
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

## 3 Composition and Information on Ingredients

### · Chemical characterisation: Mixtures

· **Description:** Mixture of substances listed below with nonhazardous additions.

### · Dangerous components:

20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate	10-<30%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	
27813-02-1	Hydroxypropyl Methacrylate	≥1-<10%
	⚠ Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	
1830-78-0	Glycerol Dimethacrylate	<10%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
94-36-0	Benzoyl Peroxide	≥0.1-<1%
	⚠ Self-react. B, H241; Org. Perox. B, H241; ⚠ Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	
79-41-4	Methacrylic Acid	≥0-<1%
	⚠ Acute Tox. 3, H311; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335; Flam. Liq. 4, H227	
	Trade Secret	≥0.1-<1%
	⚠ Skin Corr. 1B, H314; ⚠ Acute Tox. 4, H302; Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

## 4 First Aid Measures

· **General information:** Immediately remove any clothing soiled by the product.

### · After inhalation:

This product is a viscous gel, therefore chance of inhalation is extremely low.  
 Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

### · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.

### · Information for doctor:

· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire Fighting Measures

- **Suitable extinguishing agents:**  
Water spray, fog, or mist, foam, dry chemical, carbon dioxide  
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** Wear fully protective suit.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling:**  
See product labeling.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
See product labelling.  
Keep container tightly sealed.
- **Specific end use(s)** Professional dental luting & filling agent

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Ingredients with limit values that require monitoring at the workplace:**

79-41-4 Methacrylic Acid

WES Long-term value: 70 mg/m<sup>3</sup>, 20 ppm

- **Additional information:** The lists valid during the making were used as basis.

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- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

## 9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:**

Gel

- **Colour:**

Blue

- **Odour:**

Acrylic

- **Odour threshold:**

Not determined.

- **pH-value:**

Not applicable (non-aqueous)

- **Change in condition**

- **Melting point/freezing point:**

Undetermined.

- **Initial boiling point and boiling range:**

Undetermined.

- **Flash point:**

Not applicable.

- **Flammability (solid, gas):**

Not applicable.

- **Decomposition temperature:**

Not determined.

- **Auto-ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

- **Explosion limits:**

- **Lower:**

Not determined.

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· <b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.18 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with</b>	
· <b>water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
· <b>Dynamic:</b>	Not determined.
· <b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

#### · LD/LC50 values relevant for classification:

##### Trade Secret

Oral	LD50	>15,000 mg/kg (mouse) >3,300 mg/kg (rat)
	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	0.139 mg/l (rat)
<b>94-36-0 Benzoyl Peroxide</b>		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	0.0602 mg/l (Fish) (Toxicity to fish)
Inhalative	LD50 Inhalation 4hrs	24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)
<b>79-41-4 Methacrylic Acid</b>		
Oral	LD50	1,250 mg/kg (mouse)
		1,060 mg/kg (rat)
		1,200 mg/kg (rabbit)
		86 mg/l (Fish)
Dermal	LC50 Fish	86 mg/l (Fish)
		1,000 mg/kg (Guinea pig)
Dermal	LD50	1,000 mg/kg (Guinea pig)
		500 mg/kg (rabbit)

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Inhalative	LC50/4 h	7.1 mg/l (rat)
<b>Trade Secret</b>		
Oral	LD50	810 mg/kg (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

## 12 Ecological Information

### · Toxicity

· <b>Aquatic toxicity:</b>	
<b>Trade Secret</b>	
EC50	>1,000 mg/kg (daphnia)
<b>94-36-0 Benzoyl Peroxide</b>	
Algae Toxicity	0.0711 mg/l (Algae) (Toxicity to algae) 0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)
<b>79-41-4 Methacrylic Acid</b>	
EC50	17,000 mg/kg (Algae) <180 mg/kg (daphnia) (Toxicity to aquatic invertebrates)

- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

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### 14 Transport information

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not Applicable
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	not regulated

### 15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture		
· NIOSH-Ca (National Institute for Occupational Safety and Health)		
75-56-9	Methyloxirane	
14808-60-7	Silica Glass	
· Australian Inventory of Industrial Chemicals		
9005-65-6	Sorbitan Monooleate, Ethoxylated	
20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate	
27813-02-1	Hydroxypropyl Methacrylate	
	Trade Secret	
94-36-0	Benzoyl Peroxide	
7732-18-5	Water	
79-41-4	Methacrylic Acid	
	Trade Secret	
75-56-9	Methyloxirane	
97-53-0	Eugenol	
	Co-Cr-AL Spinel Blue Green	
14808-60-7	Silica Glass	
128-37-0	Butylated Hydroxytoluene	
· Standard for the Uniform Scheduling of Medicines and Poisons		
94-36-0	Benzoyl Peroxide	S2, S4, S5
75-56-9	Methyloxirane	S7
97-53-0	Eugenol	S5, S6

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· **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Chemical safety assessment:**

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

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases from Section 3**

H227 Combustible liquid.

H241 Heating may cause a fire or explosion.

H302 Harmful if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

Flam. Liq. 4: Flammable liquids – Category 4

Self-react. B: Self-reactive substances and mixtures – Type B

Org. Perox. B: Organic peroxides – Type B

Acute Tox. 4: Acute toxicity – Category 4

Acute Tox. 3: Acute toxicity – Category 3

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3