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1 Identification

- Other means of identification
- · Trade name: UltraTempTM REZ II Base
- · Article number: SDS 440-001.03R01, 1007603, 14410, 6061, S6061
- 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.

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South Jordan, UT 84095-3942

USA

onlineordersupport@ultradent.com

(800) 552-5512

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): +1 (800) 424-9300

(INTERNATIONAL): +(703) 527-3887

2 Hazard(s) Identification

· Classification of the substance or mixture



Skin corrosion/irritation – Category 2 H315 Causes skin irritation.

Eye damage/irritation - Category 2A H319 Causes serious eye irritation.

Skin sensitisation – Category 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labelling:

Hydroxypropyl Methacrylate (≥1-<10 %)

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

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(Contd. of page 1) · Precautionary statements If medical advice is needed, have product container or label at hand. P101 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. If skin irritation or rash occurs: Get medical advice/attention. P333+P313 P337+P313 If eye irritation persists: Get medical advice/attention. Dispose of contents/container in accordance with local/regional/national/international P501

3 Composition and Information on Ingredients

regulations.

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous d	components:	
20882-04-6	Mono-2-(Methacryloyloxy) Ethyl Succinate	10-<30%
	♦ Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319	
27813-02-1	Hydroxypropyl Methacrylate	≥1-<10%
	💠 Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	
1830-78-0	Glycerol Dimethacrylate	<10%
	♦ Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A, H319; Specific target organ toxicity (single exposure) – Category 3, H335	
94-36-0	Benzoyl Peroxide	≥0.1-<1%
	♦ Self-reactive substances and mixtures – Type B, H241; Organic peroxides – Type B, H241; ↑ Eye damage/irritation – Category 2A, H319; Skin sensitisation – Category 1, H317	
	Trade Secret	≥0.1-<1%
	Skin corrosion/irritation — Category 1B, H314; Acute toxicity - oral — Category 4, H302; Eye damage/irritation — Category 2A, H319; Skin sensitisation — Category 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 section 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

- · Appropriate engineering controls No further data; see section 7.
- Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- · Additional information: The lists valid during the making were used as basis.
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

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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:
 Initial boiling point and boiling range:
 Flash point:
 Flammability
 Decomposition temperature:
 Undetermined.
 Not applicable.
 Not determined.

• **Ignition temperature:** Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not determined.
Density at 20 °C: 1.18 g/cm³
Relative density Not determined.

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Vapour densityEvaporation rateNot determined.Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. Kinematic: Not determined.

· Other information

• Particle characteristics Not applicable.

· Physical state Fluid

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: 94-36-0 Benzoyl Peroxide						
	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)				
Trade Secret						
Oral	LD50	810 mg/kg (rat)				

- Primary irritant effect:
- · 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.

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12 Ecological Information

- · Toxicity
- · Aquatic toxicity:

94-36-0 Benzoyl Peroxide

Algae Toxicity 0.0711 mg/l (Algae) (Toxicity to algae)

0.11 mg/l (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:

and the IBC Code

• **Recommendation:** Disposal must be made according to official regulations.

UN-Number		
ADG, IMDG, IATA	not regulated	
UN proper shipping name		
ADG, ADN, 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	

Not applicable.

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· UN "Model Regulation":

not regulated

15 Regulatory information

	h and environmental regulations/legislation specific for the substance or <i>i</i> (National Institute for Occupational Safety and Health)		
75-56-9	Methyloxirane		
14808-60-7	Silica Glass		
Australian 1	nventory of Industrial Chemicals		
9005-65-6	Polysorbate 80 (Tween 80)		
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 S.			
75-56-9 Methyloxirane		<i>S7</i>	
97-53-0 Eugenol		S5, S6	
· Australia: P	riority 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

H241 Heating may cause a fire or explosion.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

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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

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

Organic peroxides – Type B: Organic peroxides – Type B

Acute toxicity - oral - Category 4: Acute toxicity - Category 4

Skin corrosion/irritation - Category 1B: Skin corrosion/irritation - Category 1B

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

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A

Skin sensitisation – Category 1: Skin sensitisation – Category 1

Specific target organ toxicity (single exposure) - Category 3: Specific target organ toxicity (single exposure) - Category 3

* Data compared to the previous version altered.

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