

Safety Data Sheet

according to WHS Regulations

Printing date 10.11.2023

Revision: 10.11.2023

1 Identification

- **Product identifier**
- **Trade name:** UltraTemp™ REZ II - Catalyst (Regular, Fast)
- **Article number:** SDS 439-001.02R01, 1007965, 1007604
- **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**



Skin Sens. 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:**
Triethylene Glycol Dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **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.

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- P362+P364 Take off contaminated clothing and wash it before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 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:**

109-16-0	Triethylene Glycol Dimethacrylate	10-<30%
	⚠ Skin Sens. 1, H317	
112926-00-8	Synthetic Amorphous Silica	10-<30%
99-97-8	Dimethyl-p-toluidine	<2.5%
	⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; ⚠ STOT RE 2, H373; Flam. Liq. 4, H227	

- **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:**
 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.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
 · **Most important symptoms and effects, both acute and delayed** No further relevant information available.
 · **Indication of any immediate medical attention and special treatment needed**
 No further relevant information available.

5 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

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.

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See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling:**
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.
- **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:**

112926-00-8 Synthetic Amorphous Silica

WES Long-term value: 10 mg/m³

- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **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:** Goggles recommended during refilling
- **Body protection:** Protective work clothing

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9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Viscous liquid
- **Colour:** According to product specification
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable (non-aqueous)
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** >250 °C
- **Flash point:** >150 °C
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** 255 °C
- **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.
- **Upper:** Not determined.
- **Vapour pressure at 20 °C:** 0 hPa
- **Density at 20 °C:** 1.65-1.75 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** 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** 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:		
1314-13-2 Zinc Oxide		
Oral	LD50	7,950 mg/kg (mouse)

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Inhalative	LC50 Fish	>5,000 mg/kg (rat)
	LC50/4 h	>320 mg/l (Fish)
	LC50(Daphnia magna) (static)	>5.7 mg/l (mouse)
		0.098 mg/l (daphnia)
109-16-0 Triethylene Glycol Dimethacrylate		
Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)
112926-00-8 Synthetic Amorphous Silica		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
99-97-8 Dimethyl-p-toluidine		
Oral	LC50 Fish	46-52 mg/l (Fish)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.4 mg/l (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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

· Aquatic toxicity:

1314-13-2 Zinc Oxide

EC50	2.066 mg/kg (Fish)
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109-16-0 Triethylene Glycol Dimethacrylate

EC50	>100 mg/kg (Algae)
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)

- **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 2 (German Regulation) (Self-assessment): hazardous for water
 Do not allow product to reach ground water, water course or sewage system.
 Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· **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.

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)	
None of the ingredients is listed.	
· Australian Inventory of Industrial Chemicals	
1314-13-2	Zinc Oxide
109-16-0	Triethylene Glycol Dimethacrylate
112926-00-8	Synthetic Amorphous Silica
	Trade Secret
3077-12-1	P-Tolymino Diethanol
99-97-8	Dimethyl-p-toluidine
1332-37-2	Red Iron Oxide
· Standard for the Uniform Scheduling of Medicines and Poisons	
None of the ingredients is listed.	

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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.*
· Seveso category E1 *Hazardous to the Aquatic Environment*
· Qualifying quantity (tonnes) for the application of lower-tier requirements *100 t*
· Qualifying quantity (tonnes) for the application of upper-tier requirements *200 t*
· 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.
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H317 May cause an allergic skin reaction.
H330 Fatal if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
· 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
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
· * Data compared to the previous version altered.

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