



Safety Data Sheet according to WHS Regulations

Date of issue: 03.03.2025

Revision: 03.03.2025

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1 Identification

- **Other means of identification**
- **Trade name:** UltraTemp™ REZ II - Catalyst (Regular, Fast)
- **Article number:** SDS 439-001.03R01, 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
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com
- **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 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:**
Triethylene Glycol Dimethacrylate (10-<30 %)
- **Hazard statements**
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.

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- 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.
 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.

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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	⚠ Skin sensitisation – Category 1, H317	10-<30%
112926-00-8	Synthetic Amorphous Silica		>10-≤25%

- **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 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.

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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

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

112926-00-8 Synthetic Amorphous Silica

WES	Long-term value: 10 mg/m ³ inhalable dust
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- **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

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· **Body protection:** Protective work clothing

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

Not applicable.

· Auto-ignition temperature:

255 °C

· Decomposition temperature:

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 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

· 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.

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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) > 5,000 mg/kg (rat)
	LC50 Fish	> 320 mg/l (Fish)
Inhalative	LC50/4 h	> 5.7 mg/l (mouse)
	LC50(Daphnia magna) (static)	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)

- **Primary irritant effect:**
- **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.

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- Danger to drinking water if even small quantities leak into the ground.*
- **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 | <i>not regulated</i> |
| · UN proper shipping name | |
| · ADG, ADN, IMDG, IATA | <i>not regulated</i> |
| · Transport hazard class(es) | |
| · ADG, ADN, IMDG, IATA | |
| · Class | <i>not regulated</i> |
| · Packing group | |
| · ADG, IMDG, IATA | <i>not regulated</i> |
| · Environmental hazards: | <i>Not applicable.</i> |
| · Special precautions for user | <i>Not Applicable</i> |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | <i>Not applicable.</i> |
| · UN "Model Regulation": | <i>not regulated</i> |

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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

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68187-51-9	Zinc Ferrite Brown Spinel
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· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· 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

H317 May cause an allergic skin reaction.

· 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

Skin sensitisation – Category 1: Skin sensitisation – Category 1

· * Data compared to the previous version altered.