

Printing date 02/24/2025

Reviewed on 02/24/2025

1 Identification

- · Product identifier
- · Trade name: UltraTemp[™] REZ II Catalyst (Regular, Fast)
- · Article number: SDS 439-001.03R01, 1007965, 1007604
- · 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

• Information department: 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

GHS

GHS08 Health hazard

Carcinogenicity 2 H351 Suspected of causing cancer.

GHS07

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07, GHS08
- · Signal word Warning
- *Health Hazard-determining components of labeling: Triethylene Glycol Dimethacrylate*

Dimethyl-p-toluidine

· Hazard statements

H317 May cause an allergic skin reaction.

H351 Suspected of causing cancer.

· Precautionary statements

- *P201 Obtain special instructions before use.*
- P202 Do not handle until all safety precautions have been read and understood.
- P261 Avoid breathing dust/fume/gas/mist/vapors/spray
- *P272 Contaminated work clothing must not be allowed out of the workplace.*
- *P280 Wear protective gloves/protective clothing/eye protection/face protection.*
- P302+P352 If on skin: Wash with plenty of water.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- *P321* Specific treatment (see on this label).

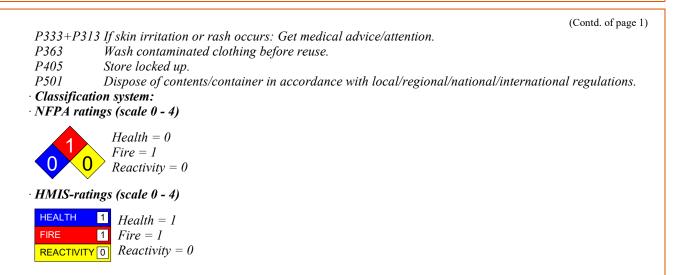
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3 Composition/information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous co	· Dangerous components:		
109-16-0	Triethylene Glycol Dimethacrylate	>10-≤25%	
112926-00-8	Synthetic Amorphous Silica	>10-≤25%	
	Trade Secret	1-10%	
99-97-8	Dimethyl-p-toluidine	≥0.1-<5%	

Additional information:

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

4 First-aid measures

· Description of first aid measures

- 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

- · Extinguishing media
- Suitable extinguishing agents: Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture No further relevant information available.

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- · Advice for firefighters
- 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.
- See Section 13 for disposal information.

7 Handling and storage

· Handling:

- **Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace. Open and handle receptacle with care. Prevent formation of aerosols.
- Information about protection against explosions and fires: Keep respiratory protective device available.
- · Conditions for safe storage, including any incompatibilities
- · 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 receptacle tightly sealed.
- · Specific end use(s) Professional dental luting & filling agent

8 Exposure controls/personal protection

- Additional information about design of technical systems: No further data; see section 7.
- · Control parameters
- Components with limit values that require monitoring at the workplace:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

112926-00-8 Synthetic Amorphous Silica

- PEL 20mppcf or 80mg/m3 /%SiO2
- *REL* Long-term value: 6 mg/m³
 - See Pocket Guide App. C
- TLV TLV withdrawn

Trade Secret

TWA Short-term value: 0.8 mg/m³

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WEEL Long-term value: 0.5 ppm

• Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

- 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.
- Store protective clothing separately.

• Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

• 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 is based 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

Information on basic physical and General Information	chemical properties	
Appearance:		
Form:	Viscous liquid	
Color:	According to product specification	
Odor:	Characteristic	
Odor threshold:	Not determined.	
pH-value:	Not applicable (non-aqueous)	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	>250 °C	
Flash point:	>150 °C	
Flammability:	Not applicable.	

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· Auto igniting:	255 °C	
· Decomposition temperature:	Not determined.	
· Ignition temperature:	Product is not selfigniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
· Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure at 20 °C:	0 hPa	
· Density at 20 °C:	1.65-1.75 g/cm ³	
· Relative density	Not determined	
· Vapor density	Not determined.	
· Evaporation rate	Not determined.	
· Solubility in / Miscibility with		
Water:	Not miscible or difficult to mix.	
· Partition coefficient (n-octanol/wa	t ter): 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.

· Chemical stability

- 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:

· LD/LC50 values that are relevant for classification:

	ATE (Acu	te Toxicity I	Estimate)
	Oral	LD50	100,000 mg/kg
		LD50	100,000 mg/kg >2,000,000 mg/kg
	Inhalative	LC50/4 h	1,400 mg/l
ĺ	109_16_07	Fri <i>o</i> thylono	Glycol Dimethacrylate

109-16-0 Trietnylene Glycol Dimetnacrylate			
	LD50	>5,000 mg/kg (rat)	
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)	
		>2,000 mg/kg (mouse)	

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112926-00)-8 Synthetic	c Amorphous Silica (Contd. of page 1997)	age
Oral	LD50	>5,000 mg/kg (rat)	
Dermal	LD50	>5,000 mg/kg (rabbit)	
Trade Sec	ret		
<i>Oral LD50</i> >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)	
99-97-8 D	imethyl-p-to	luidine	
Oral	LC50 Fish	46-52 mg/l (Fish)	
Dermal	LD50	>2,000 mg/kg (rabbit)	
Inhalative	LC50/4 h	1.4 mg/l (rat)	
Sensitizati Additional	l toxicologic	ng effect. ation possible through skin contact. c al information: following dangers according to internally approved calculation methods for preparatio	on
Carcinoge	nic categori	ies	
,		Agency for Research on Cancer)	
		n Trifluoride	3
99-97-	8 Dimethyl-	-p-toluidine	21
NTP (Nati	ional Toxico	ology Program)	
	e ingredient	s is listed.	
None of th			
v	(Occupatio	nal Safety & Health Administration)	

12 Ecological information

· Toxicity

• Aquatic toxicity:	· Aquatic toxicity:		
109-16-0 Triethy	lene Glycol Dimethacrylate		
EC50	>100 mg/kg (Algae)		
Biodegradability	28 days (Aerobic) (Biodegradability testing)		
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)		
Trade Secret			
EC50	>1,000 mg/kg (daphnia)		
· Persistence and a	legradability No further relevant information available.		
Behavior in environmental systems:			

Behavior in environmental systems:
Bioaccumulative potential No further relevant information available.

• *Mobility in soil* No further relevant information available.

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- · Additional ecological information:
- General notes:
- Water hazard class 2 (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.
- 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 packagings:
- Recommendation: Disposal must be made according to official regulations.

UN-Number DOT, IMDG, IATA	Not Populated	
DOI, IMDO, IATA	Not Regulated	
UN proper shipping name DOT, ADN, IMDG, IATA	Not Regulated	
Transport hazard class(es)		
DOT, ADN, IMDG, IATA		
Class	Not Regulated	
Packing group		
DOT, IMDG, IATA	Not Regulated	
Environmental hazards:	Not Applicable.	
Special precautions for user	Not Applicable	
Transport in bulk according to Annex	II of	
MARPOL73/78 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 No further relevant information available.

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

• Section 313 (Specific toxic chemical listings):

1314-13-2 Zinc Oxide

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TSCA (Toxic Substances Control Act):	
109-16-0 Triethylene Glycol Dimethacrylate	ACTIV
99-97-8 Dimethyl-p-toluidine	ACTIV
Hazardous Air Pollutants	4
None of the ingredients is listed.	
Proposition 65	
Chemicals known to cause cancer:	
99-97-8 Dimethyl-p-toluidine	
Chemicals known to cause reproductive toxicity for females:	
None of the ingredients is listed.	
Chemicals known to cause reproductive toxicity for males:	
None of the ingredients is listed.	
Chemicals known to cause developmental toxicity:	
None of the ingredients is listed.	
Carcinogenic categories	
EPA (Environmental Protection Agency)	
1314-13-2 Zinc Oxide	D, I, I
ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)	· · ·
13760-80-0 Ytterbium Trifluoride	A
NIOSH-Ca (National Institute for Occupational Safety and Health)	
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.

· Department issuing SDS: Environmental, Health, and Safety

- Abbreviations and acronyms:
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- 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)
- NFPA: National Fire Protection Association (USA)
- HMIS: Hazardous Materials Identification System (USA)
- 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 OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit
- Sensitization Skin 1: Skin sensitisation Category 1
- Carcinogenicity 2: Carcinogenicity Category 2
- * Data compared to the previous version altered.

[·] Contact: Customer Service

[·] Date of preparation / last revision 02/24/2025 / -