

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.03.2020

Revision: 10.03.2020

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** UltraTemp™ REZ Catalyst- Regular and Fast

· **Article number:** 15093, 15094

· **Index number:** SDS 202-001.06

· **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Non-Eugenol Temporary Luting & Filling Agent

· **Application of the substance / the mixture** Professional Dental Non-Eugenol Temporary 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

EC Responsible Person
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0

· **Further information obtainable from:** Customer Service

· **Emergency telephone number:**

CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

· **Hazard pictograms** GHS07, GHS09

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- **Signal word** Warning
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate
- **Hazard statements**
H317 May cause an allergic skin reaction.
H410 Very toxic to aquatic life with long lasting effects.
- **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.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P302+P352 IF ON SKIN: Wash with plenty of water.
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).
P391 Collect spillage.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 1314-13-2 EINECS: 215-222-5	Zinc Oxide ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	>25-≤50%
CAS: 112926-00-8 EC number: 601-214-2	Synthetic Amorphous Silica ⚠ Acute Tox. 3, H331	>10-≤25%
CAS: 109-16-0 EINECS: 203-652-6	Triethylene Glycol Dimethacrylate ⚠ Skin Sens. 1, H317	>10-≤25%
CAS: 99-97-8 EINECS: 202-805-4	Dimethyl-p-toluidine ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; ⚠ STOT RE 2, H373; Aquatic Chronic 3, H412	≤2.5%

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

4 First aid measures

- **Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
This product is a viscous liquid, therefore inhalation is extremely unlikely.
Seek medical treatment in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.

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If skin irritation continues, consult a doctor.

· **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.*

· **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** *Use fire extinguishing methods suitable to surrounding conditions.*

· **Special hazards arising from the substance or mixture** *No further relevant information available.*

· **Advice for firefighters:**

· **Protective equipment:** *Wear fully protective suit.*

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:**

Inform respective authorities in case of seepage into water course or sewage system.

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.

· **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:** *No special precautions are necessary if used correctly.*

· **Information about fire - and explosion protection:** *No special measures required.*

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** *See product labeling.*

· **Information about storage in one common storage facility:** *Not required.*

· **Further information about storage conditions:** *See product labelling.*

· **Specific end use(s)** *Professional Dental Non-Eugenol Temporary Luting & Filling Agent*

8 Exposure controls/personal protection

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

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- **Control parameters**
- **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.
- **Exposure controls**
- **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

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Viscous Liquid

Colour: Beige

· **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: >250 °C

· **Flash point:** >150 °C

· **Flammability (solid, gas):** Not applicable.

· **Ignition temperature:** 255 °C

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· 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:	1.682-1.687 g/cm ³
· 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.
· Solvent content:	
VOC (EC)	0.00 %
· Solids content:	≤50 %
· 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** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	100,000 mg/kg (rat)
Inhalative	LC50/4 h	>2.23 mg/l
1314-13-2 Zinc Oxide		
Oral	LD50	7,950 mg/kg (mouse) >5,000 mg/kg (rat)

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Inhalative	LC50 Fish	>320 mg/l (Fish)
	LC50/4 h	>5.7 mg/l (mouse)
	LC50(Daphnia magna) (static)	0.098 mg/l (daphnia)
112926-00-8 Synthetic Amorphous Silica		
Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (rat)
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)
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)

- **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.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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)
109-16-0 Triethylene Glycol Dimethacrylate	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)

- **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.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

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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.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

· 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**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**

HP13	Sensitising
HP14	Ecotoxic

· **Uncleaned packaging:**

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

14 Transport information

· **UN-Number**

· **ADR, ADN, IMDG, IATA** *not regulated*

· **UN proper shipping name**

· **ADR, ADN, IMDG, IATA** *not regulated*

· **Transport hazard class(es)**

· **ADR, ADN, IMDG, IATA**

· **Class** *not regulated*

· **Packing group**

· **ADR, 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**

· **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

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- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **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**

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

- **Department issuing SDS:** Regulatory Affairs

- **Contact:** Customer Service

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - inhalation – Category 3

Skin Sens. 1: Skin sensitisation – Category 1

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3