

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

Printing date 10.11.2023

Version number 1

Revision: 10.11.2023

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

- **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*
- EC Responsible Person
Ultradent Products GmbH
Am Westhover 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**



Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.



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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *GHS07, GHS09*
- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
Triethylene Glycol Dimethacrylate

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.11.2023

Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 1)

· 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 carefully and follow all instructions.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves.
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/information on ingredients

· Mixtures

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

· Dangerous components:

CAS: 1314-13-2	Zinc Oxide	≥25-<40%
EINECS: 215-222-5	⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
CAS: 109-16-0	Triethylene Glycol Dimethacrylate	>10-≤25%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
CAS: 99-97-8	Dimethyl-p-toluidine	<2.5%
EINECS: 202-805-4	⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; ⚠ STOT RE 2, H373; Aquatic Chronic 3, H412	

- **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:**
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.
· **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.

(Contd. on page 3)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 2)

- **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 product to reach sewage system or any water course.
 - 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.
 - 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

- **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.
- **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.
- **Specific end use(s)** Professional dental luting & filling agent

8 Exposure controls/personal protection

- **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**
 - Appropriate engineering controls** No further data; see item 7.
 - Individual protection measures, such as 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.

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.11.2023

Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 3)

· Hand protection



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/face protection** Goggles recommended during refilling

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Physical state	Fluid
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	>250 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	>150 °C
· Ignition temperature:	255 °C
· Decomposition temperature:	Not determined.
· pH	Not applicable (non-aqueous)
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Not miscible or difficult to mix.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure at 20 °C:	0 hPa
· Density and/or relative density	
· Density at 20 °C:	1.65-1.75 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 4)

- **Other information**
- **Appearance:**
- **Form:** Viscous liquid
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

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 hazard classes as defined in Regulation (EC) No 1272/2008**
- **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
Inhalative	LC50/4 h	1,400 mg/l

(Contd. on page 6)

GB

Safety data sheet
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Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 5)

1314-13-2 Zinc Oxide

Oral	LD50	7,950 mg/kg (mouse) >5,000 mg/kg (rat)
Inhalative	LC50 Fish	>320 mg/l (Fish)
	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)
Dermal	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
	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)

- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

12 Ecological information· **Toxicity**· **Aquatic toxicity:**

1314-13-2 Zinc Oxide	
EC50	2.066 mg/kg (Fish)
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.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.
- **Other adverse effects**
- **Remark:** Very toxic for fish
- **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.
Also poisonous for fish and plankton in water bodies.

(Contd. on page 7)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 10.11.2023

Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

Very toxic for aquatic organisms

(Contd. of page 6)

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 or ID number · ADR, IMDG, IATA	not regulated
· UN proper shipping name · ADR, 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
· Maritime transport in bulk according to IMO instruments	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.

- **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.

(Contd. on page 8)

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

Printing date 10.11.2023

Version number 1

Revision: 10.11.2023

Trade name: UltraTemp™ REZ II - Catalyst (Regular, Fast)

(Contd. of page 7)

· **Relevant phrases from Section 3**

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.

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:** 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

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)

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

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

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