

## Safety Data Sheet

according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

### 1 Identification

- **Product identifier**
- **Trade name:** *EndoREZ™ Catalyst*
- **Article number:** *SDS 71-001.08R02, 81231*
- **Relevant identified uses of the substance or mixture and uses advised against**  
*Professional Endodontic Canal Sealer*
- **Application of the substance / the mixture** *Professional Endodontic Canal Sealer*
- **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:**  
*Diurethane Dimethacrylate  
Triethylene Glycol Dimethacrylate*
- **Hazard statements**  
*H317 May cause an allergic skin reaction.*
- **Precautionary statements**  
*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.*

(Contd. on page 2)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

**Trade name: EndoREZ™ Catalyst**

(Contd. of page 1)

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:**

72869-86-4	Diurethane Dimethacrylate	⚠ Skin Sens. 1, H317	30-60%
109-16-0	Triethylene Glycol Dimethacrylate	⚠ Skin Sens. 1, H317	10-<30%

- **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.  
See Section 13 for disposal information.

AU

(Contd. on page 3)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

Trade name: **EndoREZ™ Catalyst**

(Contd. of page 2)

### 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:** *None.*
- **Specific end use(s)** *Professional Endodontic Canal Sealer*

### 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:**  
*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.*
- **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*

AU

(Contd. on page 4)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

Trade name: EndoREZ™ Catalyst

(Contd. of page 3)

### 9 Physical and Chemical Properties

- **General Information**
- **Appearance:**
- **Form:** Pasty
- **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:** Undetermined.
- **Flash point:** >100 °C
- **Flammability (solid, gas):** Not applicable.
- **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:** Not determined.
- **Density at 20 °C:** 1.7-1.8 g/cm<sup>3</sup>
- **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:**

72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
------	------	--------------------

(Contd. on page 5)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

Trade name: EndoREZ™ Catalyst

(Contd. of page 4)

**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)

- **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:****72869-86-4 Diurethane Dimethacrylate**

EC50 &gt;0.6 mg/kg (Algae)

Biodegradability 28 days (Aerobic) (Biodegradability testing)

**109-16-0 Triethylene Glycol Dimethacrylate**

EC50 &gt;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 1 (German Regulation) (Self-assessment): slightly hazardous for water
- Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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.

AU

(Contd. on page 6)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

Trade name: EndoREZ™ Catalyst

(Contd. of page 5)

### 14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, 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
· Australian Inventory of Industrial Chemicals
7787-59-9 Bismuth Chloride Oxide
72869-86-4 Diurethane Dimethacrylate
109-16-0 Triethylene Glycol Dimethacrylate
5743-47-5 Calcium Lactate, Pentahydrate
Trade Secret
51274-00-1 Yellow Iron Oxide
3077-12-1 P-Tolymino Diethanol
· 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.
· 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

(Contd. on page 7)

# Safety Data Sheet

## according to WHS Regulations

Printing date 07.08.2023

Revision: 07.08.2023

**Trade name: EndoREZ™ Catalyst**

(Contd. of page 6)

- **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

Skin Sens. 1: Skin sensitisation – Category 1

- **\* Data compared to the previous version altered.**

AU