# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use

EndoREZ® Base

## SECTION 1: Identification of the substance/preparation and of the company/undertaking

### 1.1. Product identifier

- **Product code**: ER/81225
- **Product name**: EndoREZ® Base
- **Product description**: Canal Sealer

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Relevant identified uses**: Professional Endodontic Canal Sealer

### 1.3. Details of the supplier of the safety data sheet

**Manufacturer**
Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095

**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

### 1.4. Emergency telephone number

- CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
- (INTERNATIONAL) : +1(703) 527 - 3887

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation(EC) No 1272/2008 [CLP]**

<table>
<thead>
<tr>
<th>Health</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute Toxicity (Inhalation)</strong>, Category 3</td>
<td></td>
</tr>
<tr>
<td><strong>Skin Irritation</strong>, Category 2</td>
<td></td>
</tr>
<tr>
<td><strong>Skin Sensitization</strong>, Category 1</td>
<td></td>
</tr>
<tr>
<td><strong>Eye Irritation</strong>, Category 2A</td>
<td></td>
</tr>
</tbody>
</table>

**Exclamation mark**

**Signal Word**
WARNING

**Hazard statement(s)**
- H315: Causes skin irritation.
- H317: May cause an allergic skin reaction.
- H335: May cause respiratory irritation.
- H319: Causes serious eye irritation.
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Precautionary statement(s)
Response:
   P305: IF IN EYES:
   P351: Rinse cautiously with water for several minutes.
   P337+P313: If eye irritation persists: Get medical advice/attention.
   P302+P352: IF ON SKIN: Wash with plenty of soap and water.
   P332+P313: If skin irritation occurs: Get medical advice/attention.
   P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Storage: P273: Avoid release to the environment.

2.3. Other hazards
Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances
Not Applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>TEGDMA</td>
<td>109-16-0</td>
<td>203-652-6</td>
<td>&lt; 20</td>
<td>Skin Sens., Cat. 1B; H317</td>
</tr>
<tr>
<td>Bismuth Chloride Oxide</td>
<td>7787-59-9</td>
<td>232-122-7</td>
<td>&lt; 50</td>
<td>Skin Irr., Cat. 2; Eye Irr., Cat. 2A; STOT SE, Cat. 3; H315; H319; H335</td>
</tr>
<tr>
<td>Calcium Lactate Pentahydrate</td>
<td>5734-47-5</td>
<td>--</td>
<td>&lt; 5</td>
<td>Not classified</td>
</tr>
<tr>
<td>Diurethane Dimethacrylate</td>
<td>72869-86-4</td>
<td>276-957-5</td>
<td>&lt; 25</td>
<td>Skin Sens., Cat. 1; H317</td>
</tr>
</tbody>
</table>

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes. : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.
Following ingestion : No specific hazards are encountered under normal product use.
Following inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.
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4.2. Most important symptoms and effects, both acute and delayed

Eyes : Causes eye irritation.
Skin : May cause skin irritation and sensitization.
Ingestion : None expected for this product.
Inhalation : May be harmful if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Carbon Dioxide

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill : Wipe up with cloth, soap and water.
Large spill : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Use suitable protective equipment.
Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Endodontic Canal Sealer

SECTION 8: Exposure controls / personal protection

8.1. Control parameters
## 8.2. Exposure controls

- **Eye/face protection**: Wear eye protection
- **Skin protection**: Wear suitable protective clothing and gloves.
- **Respiratory protection**: Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Paste</td>
</tr>
<tr>
<td>Colour</td>
<td>White to yellow tinted, semi-viscous solution</td>
</tr>
<tr>
<td>Odour</td>
<td>NAP</td>
</tr>
<tr>
<td>pH</td>
<td>NAP (non-aqueous)</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>1.7 - 1.8</td>
</tr>
</tbody>
</table>

### 9.2. Other information

Additional information: No further relevant information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

- **Reactivity**: Polymerization occurs when exposed to amine catalysts, metals, or pressure.

### 10.2. Chemical stability

- **Chemical stability**: Stable when stored and handled under recommended conditions.

### 10.3. Possibility of hazardous reactions

- **Hazardous polymerization**: None

### 10.4. Conditions to avoid

- **Conditions to avoid**: Not Determined

### 10.5. Incompatible materials

- **Incompatible materials**: Not Determined

### 10.6. Hazardous decomposition products

- **Hazardous decomposition products**: Carbon Dioxide

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

**Acute**

- **Dermal LD$_{50}$**: $>5700$ mg/kg Rabbit/Rat/Mouse
- **Oral LD$_{50}$**: $>2900$ mg/kg Rat
- **Inhalation LC$_{50}$**: $>0.5$ mg/L/4H Rat
- **Other information**: Device is biocompatible when used as directed by dental professionals per ISO
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## SECTION 12: Ecological information

### 12.1. Toxicity
- Aquatic toxicity (acute): Do not allow to enter sewers or drains that may lead to waterways.

### 12.2. Persistence and degradability
- Persistence and degradability: Not classified

### 12.3. Bioaccumulative potential
- Bioaccumulative potential: Not classified

### 12.4. Mobility in soil
- Mobility in soil: Not Available

### 12.5. Results of PBT and vPvB assessment
- Results of PBT and vPvB assessment: Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

### 12.6. Other adverse effects
- Environmental data: Do not flush to sewer.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

## SECTION 14: Transport information

### 14.1. UN number
- UN number: NAP

### 14.2. UN proper shipping name
- UN proper shipping name: Not Dangerous Goods

### 14.3. Transport hazard class(es)
- Hazard classification: NAP

### 14.4. Packing group
- Packing group: NAP

### 14.5. Environmental hazards
- Marine pollutant #1: NAP

### 14.6. Special precautions for user
- ADR - road: NAP
- RID - rail: NAP
- IMDG - sea: NAP
- IATA - air: NAP
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14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
General information : Substances of very high concern (SVHC) according to REACH, Article 57:
Contains no SVHC substances.
General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment
Chemical safety assessment : See Section 11
Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop
65.
This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text)
: Eye Irr., Cat. 2A: Eye Irritation, Category 2A
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract
Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
Skin Sens., Cat. 1: Skin Sensitization, Category 1
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by : Anu Kattoju
Revision summary : This SDS replaces the 03/19/2015 SDS. Revised: Section 1: MSDS
No. Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.
Other hazards. Section 4: INHALATION, SIGNS AND SYMPTOMS OF
OVEREXPOSURE - INHALATION. Section 5: EXPLOSION HAZARDS,
EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT,
SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 8:
PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . Section 9:
COLOR, COMMENTS, ODOR, PERCENT VOLATILE, pH, SPECIFIC
GRAVITY. Section 11: ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀
(rabbit), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat),
INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE,
GENERAL COMMENTS. Section 12: CHEMICAL FATE INFORMATION,
DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL
DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY
(ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀ ),
SECTION 12: Ecological information. Section 14: ROAD AND RAIL
(ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL
(UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information,
UN number, Packing group, ADR - road, IMDG - sea, IATA - air. Section 15:
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COMMENTS, GENERAL COMMENTS, RoHS. **Section 16: GENERAL STATEMENTS.**

General statements
NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permittable exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
AMU = Atomic Mass Unit

Manufacturer disclaimer
FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer’s knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.