

**SAFETY DATA SHEET**

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/07/2006

SDS No : 20-001.7

Date Revised : 03/19/2015

Revision No : 6

**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

**Distributor**

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 Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : Xi

**R phrases** : R36/38,R43

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

**Health** : Skin Irritation  
 Skin Sensitization

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/38: Irritating to eyes and skin.  
 R43: May cause sensitization by skin contact.

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

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**ULTRADENT**  
 PRODUCTS, INC.

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**EndoREZ® Base**

**Hazard pictogram(s)**



Exclamation  
mark

**Signal Word**

: WARNING

**Hazard statement(s)**

: H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.

**Precautionary statement(s)**

**Prevention**

: P280: Wear protective gloves/protective clothing/eye protection/face protection.

**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.

**Storage**

: P273: Avoid release to the environment.

**Disposal**

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns**

: No other adverse human effects.

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
TEGDMA	109-16-0	203-652-6	< 20	Xi; R43	H317
Bismuth Chloride Oxide	7787-59-9	232-122-7	< 50	Xi; R36/37/38	H315; H319; H335; H413
Calcium Lactate Pentahydrate	5734-47-5	-	< 5	Xi; R36/37/38; R22	Not classified
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 25	Xi; R36/37/38	H317; H319; H411; H315; H335

For full text of H-statements and R-phrases: 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.

**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** : None expected for this product.

**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** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

- Hazardous combustion products** : Carbon Dioxide

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**Explosion hazards** : Not Determined  
**Fire explosion** : Not Determined  
**Sensitive to static discharge** : Not Determined  
**Sensitivity to impact** : Not Determined

**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.  
**Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

**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**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection  
**Skin protection** : Wear suitable protective clothing and gloves.

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**EndoREZ® Base****Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

**Physical state** : Paste  
**Colour** : White  
**Odour** : Acrylic

**9.2. Other information****Percent volatile** : Not Determined**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****Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.**SECTION 12: Ecological information****12.1. Toxicity****Toxicity** : Water pollutant**Aquatic toxicity (acute)****96-hour LC<sub>50</sub>** : Not Determined**48-hour EC<sub>50</sub>** : Not Determined

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**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not Determined

**12.4. Mobility in soil**

**Mobility in soil** : Not Determined

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Not Determined

**12.6. Other adverse effects**

**Environmental data** : Biodegradable

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : Not Dangerous Goods

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

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**EndoREZ® Base****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****RoHS** : Please refer to Medical Devices Directive 93/42/EEC**15.2. Chemical safety assessment****Chemical safety assessment** : See Section 11**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 R43: May cause sensitization by skin contact.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.  
 H335: May cause respiratory irritation.  
 H411: Toxic to aquatic life with long lasting effects.  
 H413: May cause long lasting harmful effects to aquatic life.

**Prepared by** : Anu Kattoju**Revision summary** : This SDS replaces the 03/02/2015 SDS. Revised: **Section 1:**  
**Section 2:** . **Section 16:** GENERAL STATEMENTS.**General statements** : N/A= Not Applicable**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.

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Revision No : 5

**EndoREZ® Catalyst****SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

**Product code** : EZ/ 81231  
**Product name** : EndoREZ® Catalyst  
**Product description** : Polymerization accelerator for EndoRez

**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

**Distributor**

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 Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Danger symbols** : Xi  
**R phrases** : R36/37/38,R43

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

**Health** : Skin Irritation  
 Skin Sensitization

**2.2. Label elements****Classification according to Directive 1999/45/EC**

**Hazard pictogram(s)** : Xi



Irritant

**R&S statement(s)** : R36/37/38: Irritating to eyes, respiratory system and skin.  
 R43: May cause sensitization by skin contact.

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




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**EndoREZ® Catalyst**

<b>Hazard pictogram(s)</b>	:	 Exclamation mark
<b>Signal Word</b>	:	WARNING
<b>Hazard statement(s)</b>	:	H315: Causes skin irritation. H332: Harmful if inhaled. H317: May cause an allergic skin reaction.
<b>Precautionary statement(s)</b>		
<b>Prevention</b>	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	:	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. P301: IF SWALLOWED: P315: Get immediate medical advice/attention. P331: Do NOT induce vomiting. P304: IF INHALED: P313: Get medical advice/attention. P341: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
<b>Storage</b>	:	P273: Avoid release to the environment.
<b>Disposal</b>	:	P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**2.3. Other hazards**

**Immediate concerns** : Not Applicable

**SECTION 3: Composition / information on ingredients**

**3.1. Substances**

Not Applicable

**3.2. Mixtures**

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Bismuth Chloride Oxide	7787-59-9	232-122-7	< 50	Xi; R36/37/38	H315; H319; H335; H413
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 20	Xi; R43	H317
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 30	Xi; R36/37/38	H317; H319; H411; H315; H335
Calcium Lactate Pentahydrate	5734-47-5	-	< 5	Xi; R36/37/38; R22	Not classified

For full text of H-statements and R-phrases: 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** : If swallowed, Do Not Induce Vomiting- Seek Medical Advice.
- Following inhalation** : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**

- Eyes** : Causes eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : May be harmful if swallowed.
- Inhalation** : Maybe 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** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

- Hazardous combustion products** : None known.

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**EndoREZ® Catalyst**

**Explosion hazards** : Not Determined  
**Fire explosion** : Not Determined  
**Sensitive to static discharge** : Not Determined  
**Sensitivity to impact** : Not Determined

**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.  
**Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO<sub>2</sub>)

**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**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection  
**Skin protection** : Wear suitable protective clothing and gloves.

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**Respiratory protection** : In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

**Physical state** : Liquid  
**Colour** : Colorless to light tan  
**Odour** : Acrylic

**9.2. Other information**

**Percent volatile** : Not Determined

**SECTION 10: Stability and reactivity****10.1. Reactivity**

**Reactivity** : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

**10.2. Chemical stability**

**Chemical stability** : Stable.

**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**

**Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information****12.1. Toxicity**

**Toxicity** : Water pollutant

**Aquatic toxicity (acute)**

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

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**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Not Determined

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not Determined

**12.4. Mobility in soil**

**Mobility in soil** : Not Determined

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Not Determined

**12.6. Other adverse effects**

**Environmental data** : Biodegradable

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : Not Dangerous Goods

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

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**EndoREZ® Catalyst****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****RoHS** : Please refer to Medical Devices Directive 93/42/EEC**15.2. Chemical safety assessment****Chemical safety assessment** : See Section 11**SECTION 16: Other information**

**Relevant R-phrases and/or H-statements (number and full text)** : R22: Harmful if swallowed.  
 R36/37/38: Irritating to eyes, respiratory system and skin.  
 R43: May cause sensitization by skin contact.  
 H315: Causes skin irritation.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.  
 H335: May cause respiratory irritation.  
 H411: Toxic to aquatic life with long lasting effects.  
 H413: May cause long lasting harmful effects to aquatic life.

**Prepared by** : Anu Kattoju**Revision summary** : This SDS replaces the 03/02/2015 SDS. Revised: **Section 1:**  
**Section 2:** .**General statements** : N/A= Not Applicable**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.