

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use

ULTRADENT
PRODUCTS, INC.

Date Issued : 02/07/2006
SDS No : 20-001.8
Date Revised : 11/02/2016
Revision No : 7

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]

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

Health : Acute Toxicity (Inhalation), Category 3
Skin Irritation, Category 2
Skin Sensitization, Category 1
Eye Irritation, Category 2A

2.2. Label elements

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

Hazard pictogram(s) :



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)

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.
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.

Disposal : P501: Dispose of in compliance with governmental regulation.(EC1975L0442-20/11/2003)

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

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

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

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Control parameters : None

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

Physical state : Paste
 Colour : White to yellow tinted, semi-viscous solution
 Odour : NAP
 pH : NAP (non-aqueous)
 Specific gravity : 1.7 - 1.8

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 LD₅₀ : > 5700 mg/kg Rabbit/Rat/Mouse
 Oral LD₅₀ : > 2900 mg/kg Rat
 Inhalation LC₅₀ : > 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

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

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.