

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 09/11/2008

SDS No : 115-001.2

Date Revised : 08/12/2015

Revision No : 1

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

Product code : 1832, 1833, 1631, 1632, 1633, 1675, 1676, 1705, 1834, 1835, 1836, 1837, 3355, 3356

Product name : EndoREZ® Points

Product description : Resin coated Gutta Percha Points

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

Relevant identified uses : Professional Root Canal Filling Material

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, Category 2
Skin Sensitization, Category 1

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.

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ULTRADENT
PRODUCTS, INC.

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

Hazard pictogram(s) :



Exclamation
mark

Signal Word :

DANGER

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.

Storage :

P273: Avoid release to the environment.

Disposal :

P501: Dispose of in compliance with governmental regulation.
(EC1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns :

None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
Poly(ethylene glycol) diacrylate	26570-48-9	N/A	< 1	Xi; R36/37/38; R22; R43	Skin Irr.,Cat. 2; Skin Sens.,Cat. 1; EYE DMG.,Cat. 1; H302; H315; H317; H318

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

SECTION 4: First aid measures

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4.1. Description of first aid measures

- Following eyes** : Flush eyes with water for 5 minutes. Get medical attention if irritation develops or persists.
- Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- 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.

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

- Eyes** : May cause mechanical irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : May be harmful if swallowed in large quantities.
- 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** : None known.
- 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** : Foam, dry chemical, carbon dioxide (CO₂).

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** : Not Applicable

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6.3. Methods and material for containment and cleaning up

Large spill : Shovel or vacuum spill and place in a container for disposal.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.

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 Root Canal Filling Material

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.

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 : Solid

Colour : Color dependent

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

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10.4. Conditions to avoid

Conditions to avoid : Strong acids, strong bases, and oxidizing agents.

10.5. Incompatible materials

Incompatible materials : Not Applicable

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon Monoxide, Carbon Dioxide, Hydrocarbons, Zinc

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

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : 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 : Not readily degradable.

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

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EndoREZ® Points**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 : N/A

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**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

Additional information : This product is not considered dangerous for transportation

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.
 EYE DMG., Cat. 1: Eye Damage, Category 1
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 Skin Sens., Cat. 1: Skin Sensitization, Category 1
 H302: Harmful if swallowed.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 09/11/2008 SDS. Revised: **Section 1:** Date-Revised.

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General statements

: N/A= Not Applicable

Additional SDS information

: Revision #:1

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.