

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/08/2012

SDS No : 147-001.6

Date Revised : 04/10/2015

Revision No : 5

EndoREZ® Accelerator

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

1.1. Product identifier

Product code : EY/12050
Product name : EndoREZ® Accelerator
Product description : Polymerization accelerator for EndoRez

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

Relevant identified uses : Professional Dental Polymerization Accelerator

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 : T,Xi



R phrases : R23/24/25,R43

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

Health : Acute Toxicity (Dermal), Category 3
 Acute Toxicity (Inhalation), Category 3
 Acute Toxicity (Oral), Category 3
 Skin Sensitization

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : T

Toxic Xi

Irritant

R&S statement(s) : R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.

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ULTRADENT
 PRODUCTS, INC.

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R43: May cause sensitization by skin contact.

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

Hazard pictogram(s)



Signal Word

: DANGER

Hazard statement(s)

: H331: Toxic if inhaled.
 H301: Toxic if swallowed.
 H311: Toxic in contact with skin.
 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.
 P301: IF SWALLOWED:
 P331: Do NOT induce vomiting.
 P304: IF INHALED:
 P315: Get immediate 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

: Toxic by inhalation, skin contact and ingestion.

Physical hazards

: Harmful to aquatic life with long lasting 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]
DMPT	99-97-8	202-805-4	50	T; R23/24/25; R33; R52/53	Aquatic Tox., Cat. 3; Acute Tox. (D), Cat. 3; Acute Tox. (O), Cat. 3; STOT RE, Cat. 2; H301; H311; H331; H373; H412
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	50	Xi; R43	H317

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** : May cause mild irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : Harmful if swallowed.
- Inhalation** : Harmful if inhaled

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

- Notes to physician** : Toxic by inhalation, skin contact and ingestion.

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

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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 : Water spray, fog, or mist, 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 : 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 : Stable when stored and handled under recommended conditions.
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 Dental Polymerization Accelerator

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

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Skin protection : Avoid contact with skin.
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 : Liquid
Colour : Tinted Liquid
Odour : Pungent

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

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)

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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 : 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 : 2810

14.2. UN proper shipping name

UN proper shipping name : Toxic liquid, Organic, n.o.s. (N , N Dimethyl-p-Toluidine)

14.3. Transport hazard class(es)

Hazard classification : 6.1

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : N/A

RID - rail : N/A

IMDG - sea : N/A

IATA - air : N/A

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

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Transport in bulk : N/A

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

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.
 R33: Danger of cumulative effects.
 R43: May cause sensitization by skin contact.
 R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 Acute Tox. (D), Cat. 3: Acute Toxicity (Dermal), Category 3
 Acute Tox. (O), Cat. 3: Acute Toxicity (Oral), Category 3
 Aquatic Tox., Cat. 3: Aquatic Toxicity, Category 3
 STOT RE, Cat. 2: Target Organ Toxicity (Repeated exposure), Category 2
 H301: Toxic if swallowed.
 H311: Toxic in contact with skin.
 H317: May cause an allergic skin reaction.
 H331: Toxic if inhaled.
 H373: May cause damage to organs through prolonged or repeated exposure .
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 11/06/2012 SDS. Revised: **Section 1:** GENERAL USE. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS PHYSICAL HAZARDS. **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN . **Section 9:** PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, INCOMPATIBLE MATERIALS, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID) - SPECIAL PROVISIONS VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only)

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(CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** RoHS, SECTION 15: Regulatory information. **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.