

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 10/08/2012

SDS No : 147-001.7

Date Revised : 04/03/2017

Revision No : 6

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. Ultradent Drive (10200 South)
 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 : Skin Sensitization, Category 1
 Acute Toxicity (Dermal), Category 4
 Acute Toxicity (Inhalation), Category 4

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation
 mark

Signal Word : WARNING

Hazard statement(s) : H317: May cause an allergic skin reaction.
 H412: Harmful to aquatic life with long lasting effects.
 H332: Harmful if inhaled.
 H312: Harmful in contact with skin.

Precautionary statement(s)

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- Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P273: Avoid release to the environment.
P271: Use only outdoors or in a well-ventilated area.
- 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.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P363: Wash contaminated clothing before reuse.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P314: Get medical advice/attention if you feel unwell.
- Storage** : P405: Store locked up.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
- Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

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]
Dimethyl-p-toluidine	99-97-8	202-805-4	50	Acute Tox. (D), Cat 3; Acute Tox. (O), Cat 3; Aquatic Tox., Cat 3; STOT RE, Cat. 2; H227; H301; H331; H311; H412; H317
TEGDMA	109-16-0	203-652-6	50	Skin Sens., Cat. 1B; 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** : Immediately flush skin with plenty of water. Remove clothing. Get medical attention if symptoms occur. Wash clothing separately before reuse.
- Following ingestion** : If swallowed rinse mouth out with water. Seek medical attention if you feel unwell.

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Following inhalation : Rest in the fresh air and seek medical advice if necessary.

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

Eyes : May cause mild irritation.
Skin : May cause skin irritation and sensitization.
Ingestion : May be harmful if swallowed.
Inhalation : May be harmful if inhaled.

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

Notes to physician : NAP

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 : None known.

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 : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.
Handling : Use suitable protective clothing.
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

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SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Dimethyl p toluidine CAS: 99-97-8
TWA WEEL: 0.5ppm

8.2. Exposure controls

Eye/face protection : Wear eye protection .
Skin protection : Wear suitable protective clothing and gloves.
Respiratory protection : Use only in a well ventilated area.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Low viscosity clear liquid
Odour : Acrid Aromatic
pH : NAP (non-aqueous)
Specific gravity : 1.0

9.2. Other information

Additional information : No further relevant information available

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

10.4. Conditions to avoid

Conditions to avoid : Not Available

10.5. Incompatible materials

Incompatible materials : Not Available

10.6. Hazardous decomposition products

Hazardous decomposition products : Carbon Dioxide

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 2000 mg/kg Mouse/Rabbit

Notes : < 1% of the mixture consists of components of unknown toxicity Dermal.

Oral LD₅₀ : > 5000 mg/kg Rat

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Notes	: 50% of the mixture consists of components of unknown toxicity (Oral).
Inhalation LC ₅₀	: > 1.4 mg/L/4H Rat
Notes	: ~50% of the mixture consists of components of unknown toxicity (Inhalation).
Germ cell mutagenicity	: Dimethyl-p-Toluidine is mentioned as a mutagen on the raw material SDS.
Carcinogenicity	: Dimethyl-p-Toluidine is listed as a carcinogen on IARC, and CA Prop 65.
Reproductive toxicity	: Based on available data, the classification criteria are not met
Other information	: Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not empty into drains or the aquatic environment.

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 classified

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 : No further relevant information available.

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

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Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP
RID - rail : NAP
IMDG - sea : NAP
IATA - air : NAP

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 : WARNING! This product contains a chemical known to the State of California to cause cancer on the CA Prop 65 List. Dimethyl-p-Toluidine.
WARNING! IARC has listed Dimethyl-p-Toluidine as a group 2B carcinogen.

SECTION 16: Other information

Relevant H-statements (number and full text) : 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
Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
H227: Combustible liquid.
H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H317: May cause an allergic skin reaction.
H331: Toxic if inhaled.
H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/10/2015 SDS. Revised: **Section 1**: Date-Revised.

General statements : NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permissible exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average

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PPE = Personal Protective Equipment

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.