

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 28.04.2020

Revision: 25.02.2020

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** EndoREZ™ Accelerator
- **Article number:** 12050
- **Index number:** SDS 147-001.09
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Polymerization Accelerator
- **Application of the substance / the mixture** Professional Dental Polymerization Accelerator
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com

- EC Responsible Person
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0

- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS06 skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H331 Toxic if inhaled.



GHS08 health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

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- **Label elements**

- **Labelling according to Regulation (EC) No 1272/2008**

The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- **Hazard pictograms GHS06, GHS08**

- **Signal word Danger**

- **Hazard-determining components of labelling:**

Dimethyl-p-toluidine

Triethylene Glycol Dimethacrylate

- **Hazard statements**

H301+H331 Toxic if swallowed or if inhaled.

H317 May cause an allergic skin reaction.

H373 May cause damage to organs through prolonged or repeated exposure.

H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.

P321 Specific treatment (see on this label).

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P311 Call a POISON CENTER/doctor.

P314 Get medical advice/attention if you feel unwell.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P403+P233 Store in a well-ventilated place. Keep container tightly closed.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.



- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterisation: Mixtures**

- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 99-97-8	Dimethyl-p-toluidine	≤50%
EINECS: 202-805-4	 Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331;  STOT RE 2, H373; Aquatic Chronic 3, H412	

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CAS: 109-16-0 Triethylene Glycol Dimethacrylate

EINECS: 203-652-6  Skin Sens. 1, H317

≤50%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**

- **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

Remove breathing equipment only after contaminated clothing have been completely removed.

In case of irregular breathing or respiratory arrest provide artificial respiration.

- **After inhalation:**

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.

- **After swallowing:** Do not induce vomiting; call for medical help immediately.

- **Information for doctor:**

- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Firefighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **Special hazards arising from the substance or mixture**

During heating or in case of fire poisonous gases are produced.

- **Advice for firefighters:**

- **Protective equipment:**

Wear fully protective suit.

Mouth respiratory protective device.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

Wear protective equipment. Keep unprotected persons away.

Mount respiratory protective device.

- **Environmental precautions:**

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

- **Reference to other sections**

See Section 7 for information on safe handling.

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See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:**
 - Ensure good ventilation/exhaustion at the workplace.
 - Open and handle receptacle with care.
 - Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Provide ventilation for receptacles.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
 - See product labelling.
 - Keep container tightly sealed.
- **Specific end use(s)** Professional Dental Polymerization Accelerator

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
 - The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 - Keep away from foodstuffs, beverages and feed.
 - Immediately remove all soiled and contaminated clothing.
 - Wash hands before breaks and at the end of work.
 - Store protective clothing separately.
- **Respiratory protection:**
 - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

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· **Penetration time of glove material**

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**

Tightly sealed goggles

· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Liquid
· Colour:	Clear
· Odour:	Aromatic
· Odour threshold:	Not determined.

· **pH-value:** Not applicable (non-aqueous)· **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable.· **Flammability (solid, gas):** Not applicable.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.· **Explosion limits:**

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapour pressure:** Not determined.

· Density at 20 °C:	1 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· **Solubility in / Miscibility with water:**

Not miscible or difficult to mix.

· **Partition coefficient: n-octanol/water:** Not determined.· **Viscosity:**

· Dynamic:	Not determined.
· Kinematic:	Not determined.

· **Solvent content:**

VOC (EC) ≤50.00 %

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· **Other information**

No further relevant information available.

10 Stability and reactivity

- **Reactivity** Stable
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity**
Toxic if swallowed or if inhaled.

· **LD/LC50 values relevant for classification:****ATE (Acute Toxicity Estimates)**

Oral	LD50	200 mg/kg
Inhalative	LC50/4 h	2.8 mg/l (rat)

99-97-8 Dimethyl-p-toluidine

Oral	LC50 Fish	46-52 mg/l (Fish)
Dermal	LD50	>2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	1.4 mg/l (rat)

109-16-0 Triethylene Glycol Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	16.4 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (mouse)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

109-16-0 Triethylene Glycol Dimethacrylate

Biodegradability	28 days (Aerobic) (Biodegradability testing)
Aqua toxicity	32 mg/l (daphnia) (No Observed Effect Concentration)
EC50	>100 mg/l (Algae) (Toxicity to algae)

- **Persistence and degradability** No further relevant information available.

- **Behaviour in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **Ecotoxicological effects:**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Harmful to aquatic organisms

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP6	Acute Toxicity
HP13	Sensitising
HP14	Ecotoxic

- **Uncleaned packaging:**

- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**

- **ADR, IMDG, IATA**

UN2810

- **UN proper shipping name**

- **ADR**

2810 TOXIC LIQUID, ORGANIC, N.O.S. (Dimethyl-p-toluidine)

- **IMDG, IATA**

TOXIC LIQUID, ORGANIC, N.O.S. (Dimethyl-p-toluidine)

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· **Transport hazard class(es)**· **ADR, IMDG, IATA**· **Class**

6.1 Toxic substances.

· **Label**

6.1

· **Packing group**· **ADR, IMDG, IATA**

III

· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Warning: Toxic substances.

· **Hazard identification number (Kemler code):**

60

· **EMS Number:**

F-A,S-A

· **Stowage Category**

A

· **Stowage Code**

SW2 Clear of living quarters.

· **Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**· **ADR**· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

2

· **Tunnel restriction code**

E

· **IMDG**· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **UN "Model Regulation":**

UN 2810 TOXIC LIQUID, ORGANIC, N.O.S. (DIMETHYL-P-TOLUIDINE), 6.1, III

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **Directive 2012/18/EU**· **Seveso category H2 ACUTE TOXIC**· **Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t**· **Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t**· **REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3**· **Chemical safety assessment:**

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

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.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - oral – Category 3

Skin Sens. 1: Skin sensitisation – Category 1

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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