

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

Printing date 11.04.2019

Revision: 11.04.2019

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

- **Product identifier**
- **Trade name:** EndoREZ™ Base
- **Article number:** 81225, 71040
- **Index number:** SDS 20-001.10
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Endodontic Canal Sealer
- **Application of the substance / the mixture** Professional Endodontic Canal Sealer
- **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**



GHS07

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

- **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** GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diurethane Dimethacrylate
Triethylene Glycol Dimethacrylate
Organophosphine Oxide
Benzoyl Peroxide

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- **Hazard statements**

H317 May cause an allergic skin reaction.

- **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.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P280 Wear protective gloves.

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

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

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: 72869-86-4	Diurethane Dimethacrylate	>10-≤25%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317	
CAS: 109-16-0	Triethylene Glycol Dimethacrylate	>10-≤25%
EINECS: 203-652-6	⚠ Skin Sens. 1, H317	
	Trade Secret	≤2.5%
	⚠ Skin Corr. 1A, H314	
CAS: 162881-26-7	Organophosphine Oxide	≤2.5%
ELINCS: 423-340-5	⚠ Skin Sens. 1, H317; Aquatic Chronic 4, H413	
CAS: 94-36-0	Benzoyl Peroxide	≤2.5%
EINECS: 202-327-6	⚠ Org. Perox. B, H241; ⚠ Aquatic Chronic 1, H410; ⚠ Eye Irrit. 2, H319; ⚠ Skin Sens. 1, H317	

- **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.

- **After inhalation:**

Supply fresh air and to be sure call for a 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.

- **After swallowing:** If symptoms persist consult doctor.

- **Information for doctor:**

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

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** 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).
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** See product labelling.
- **Specific end use(s)** Professional Endodontic Canal Sealer

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:**
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.

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· **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.

· **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:** Goggles recommended during refilling

· **Body protection:** Protective work clothing

9 Physical and chemical properties

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

Form:	Pasty
Colour:	Yellow tint
Odour:	Acrylic
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.

· **Ignition temperature:** 445 °C

· **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 at 20 °C:** 0 hPa

Density at 20 °C:	1.7-1.8 g/cm ³
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

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· 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)	0.00 %
· Solids content:	<85.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **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:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Inhalative	LC50/4 h	3.95 mg/l (rat)
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72869-86-4 Diurethane Dimethacrylate

Oral	LD50	>5,000 mg/kg (rat)
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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)

162881-26-7 Organophosphine Oxide

Oral	LD50	>2,000 mg/kg (rat)
	LC50 Fish	>0.09 mg/l (Fish) (Toxicity to fish)
Dermal	LD50	>2,000 mg/kg (rat)

94-36-0 Benzoyl Peroxide

Oral	LD50	>5,000 mg/kg (rat)
	LC50 Fish	0.0602 mg/l (Fish) (Toxicity to fish)
Inhalative	LD50 Inhalation 4hrs	24.3 mg/l (rat) (Testing of Chemicals Acute Toxicity Inhalation)

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

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- **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 (carcinogenity, 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** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

· Toxicity

· Aquatic toxicity:	
72869-86-4 Diurethane Dimethacrylate	
Biodegradability	28 days (Aerobic) (Biodegradability testing)
EC50	>0.6 mg/l (Algae) (Toxicity to algae) >1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)
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)
162881-26-7 Organophosphine Oxide	
EC50 (static)	>1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity	≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
Toxicity to Aquatic Plants (static)	>0.26 mg/l (Plant) (Toxicity to algae)
94-36-0 Benzoyl Peroxide	
Algae Toxicity	0.0711 mg/l (Algae) (Toxicity to algae) 0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)

- **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.
- **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.
- **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.

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· **European waste catalogue**

HP 13 | Sensitising

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**14 Transport information**· **UN-Number**· **ADR, ADN, IMDG, IATA** not regulated· **UN proper shipping name**· **ADR, ADN, IMDG, IATA** not regulated· **Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class** not regulated· **Packing group**· **ADR, IMDG, IATA** not regulated· **Environmental hazards:**

Not applicable.

· **Special precautions for user**

Not applicable.

· **Stowage Category**

A

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

Not applicable.

· **UN "Model Regulation":**

not regulated

15 Regulatory information· **Safety, health and environmental regulations/legislation specific for the substance or mixture**· **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

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**

H241 Heating may cause a fire or explosion.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Regulatory Affairs· **Contact:** Customer Service

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· 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

Org. Perox. B: Organic peroxides – Type B

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

GB2