

Safety Data Sheet
according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

1 Identification

- **Product identifier**
- **Trade name:** *EndoREZ™ Points*
- **Article number:** *SDS 115-001.05R02, 1632, 1633, 1675, 3355, 1631, 3356*
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Root Canal Filling Material
- **Application of the substance / the mixture** *Professional Root Canal Filling Material*
- **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
Ultradent Australia Pty Ltd.
Level 22/2 Market Street
Sydney NSW 2000
Australia
Email: info.anz@ultradent.com
Toll Free: 1-800-290929
- **Further information obtainable from:** *Customer Service*
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

2 Hazard(s) Identification

- **Classification of the substance or mixture**

*health hazard**Repr. 1A H360 May damage fertility or the unborn child.**Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS07, GHS08*
- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
Toluene
Benzoyl Peroxide
- **Hazard statements**
H317 May cause an allergic skin reaction.

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H360 May damage fertility or the unborn child.

- **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.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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

P405 Store locked up.

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

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**

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

- **Dangerous components:**

94-36-0	Benzoyl Peroxide ⚠️⚠️ Self-react. B, H241; Org. Perox. B, H241; ⚠️ Serious eye damage/irritation – Category 2A, H319; Skin Sens. 1, H317	≥1-<10%
108-88-3	Toluene ⚠️ Flam. Liq. 2, H225; ⚠️ Repr. 1A, H360; STOT RE 2, H373; Asp. Tox. 1, H304; ⚠️ Skin Irrit. 2, H315; STOT SE 3, H336	≥0.3-<10%
162881-26-7	Organophosphine Oxide ⚠️ Skin Sens. 1, H317	≥0.1-<1%

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

4 First Aid Measures

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

Seek medical treatment in case of complaints.

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:**

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** If swallowed in large quantities seek medical attention.

- **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 Fire Fighting Measures

- **Suitable extinguishing agents:**

Foam, dry chemical, carbon dioxide

Use fire extinguishing methods suitable to surrounding conditions.

- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Protective equipment:** Wear fully protective suit.

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:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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:**
Avoid release to the environment
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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.
Keep container tightly sealed.
- **Specific end use(s)** Professional Root Canal Filling Material

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Ingredients with limit values that require monitoring at the workplace:**

94-36-0 Benzoyl Peroxide

WES	Long-term value: 5 mg/m ³
	Sen

108-88-3 Toluene

WES	Short-term value: 574 mg/m ³ , 150 ppm
	Long-term value: 191 mg/m ³ , 50 ppm
	Sk

- **Additional information:** The lists valid during the making were used as basis.
- **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.

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- **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.

- **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:** Not required.

- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:**

Solid

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **pH-value:**

Not applicable.

- **Change in condition**

- **Melting point/freezing point:**

Undetermined.

- **Initial boiling point and boiling range:**

Undetermined.

- **Flash point:**

Not applicable.

- **Flammability (solid, gas):**

Not determined.

- **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 applicable.

- **Density:**

Not determined.

- **Relative density**

Not determined.

- **Vapour density**

Not applicable.

- **Evaporation rate**

Not applicable.

- **Solubility in / Miscibility with**

- **water:**

Insoluble.

- **Partition coefficient: n-octanol/water:**

Not determined.

- **Viscosity:**

- **Dynamic:**

Not applicable.

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|----------------------------|--|
| · Kinematic: | Not applicable. |
| · Other information | No further relevant information available. |

10 Stability and Reactivity

- **Reactivity Stable**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** Strong acids, strong bases, and oxidizing agents.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
Zinc
Carbon monoxide and carbon dioxide

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:**

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)

108-88-3 Toluene

Oral	LD50	5,000 mg/kg (rat)
Dermal	LD50	12,124 mg/kg (rabbit)
Inhalative	LC50/4 h	5,320 mg/l (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)

- **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.
- **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** May damage fertility or the unborn child.
- **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.

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12 Ecological Information

- **Toxicity**

· Aquatic toxicity:	
94-36-0 Benzoyl Peroxide	
Algae Toxicity	0.0711 mg/l (Algae) (Toxicity to algae) 0.11 mg/l (daphnia) (Toxicity to aquatic invertebrates)
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)

- **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**
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· ADG, ADN, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, ADN, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.

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| · Special precautions for user | Not Applicable |
| · 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**

- **Australian Inventory of Industrial Chemicals**

94-36-0	Benzoyl Peroxide
108-88-3	Toluene
26570-48-9	Poly(ethylene glycol) Diacrylate
162881-26-7	Organophosphine Oxide
5124-30-1	Dicyclohexylmethane- 4,4' Diisocyanate
868-77-9	2-Hydroxyethyl Methacrylate

- **Standard for the Uniform Scheduling of Medicines and Poisons**

94-36-0	Benzoyl Peroxide		S2, S4, S5
108-88-3	Toluene		S6
868-77-9	2-Hydroxyethyl Methacrylate		S5

- **Australia: Priority Existing Chemicals**

None of the ingredients is listed.

- **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

- **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 from Section 3**

H225 Highly flammable liquid and vapour.

H241 Heating may cause a fire or explosion.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

H360 May damage fertility or the unborn child.

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

- **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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*IATA: International Air Transport Association**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)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**vPvB: very Persistent and very Bioaccumulative**Flam. Liq. 2: Flammable liquids – Category 2**Self-react. B: Self-reactive substances and mixtures – Type B**Org. Perox. B: Organic peroxides – Type B**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A**Skin Sens. 1: Skin sensitisation – Category 1**Repr. 1A: Reproductive toxicity – Category 1A**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3**STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2**Asp. Tox. 1: Aspiration hazard – Category 1**· * Data compared to the previous version altered.*

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