

Safety Data Sheet
acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

1 Identification

- **Product identifier**
- **Trade name:** *EndoREZ™ Points*
- **Article number:** *SDS 115-001.05, 1632, 1633, 1675, 3355, 1631, 3356*
- **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*
- **Information department:** *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**

*GHS08 Health hazard**Repr. 2 H361 Suspected of damaging fertility or the unborn child.**GHS07**Skin Sens. 1 H317 May cause an allergic skin reaction.*

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS07, GHS08*
- **Signal word** *Warning*
- **Health Hazard-determining components of labeling:**
*Benzoyl Peroxide
Poly(ethylene glycol) Diacrylate
Organophosphine Oxide*
- **Hazard statements**
*May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.*
- **Precautionary statements**
*P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing dust/fume/gas/mist/vapors/spray
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 If on skin: Wash with plenty of water.*

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 1)

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

P321 Specific treatment (see on this label).

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

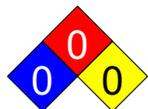
P363 Wash contaminated clothing before reuse.

P405 Store locked up.

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

HEALTH 0

Health = 0

FIRE 0

Fire = 0

REACTIVITY 0

Reactivity = 0

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

94-36-0	Benzoyl Peroxide ⚠️ Org. Perox. B, H241; ⚠️ Eye Irrit. 2A, H319; Skin Sens. 1, H317	≥1-<10%
108-88-3	Toluene ⚠️ Flam. Liq. 2, H225; ⚠️ Repr. 2, H361; STOT RE 2, H373; Asp. Tox. 1, H304; ⚠️ Skin Irrit. 2, H315; STOT SE 3, H336	≥0.1-<10%
26570-48-9	Poly(ethylene glycol) Diacrylate ⚠️ Eye Dam. 1, H318; ⚠️ Skin Irrit. 2, H315; Skin Sens. 1, H317	≥0.1-<1%
162881-26-7	Organophosphine Oxide ⚠️ Skin Sens. 1, H317	≥0.1-<1%

4 First-aid measures

· **Description of first aid measures**

· **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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 2)

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

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
Foam, dry chemical, carbon dioxide
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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 protection against explosions and fires:** Keep respiratory protective device available.
- **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.
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Root Canal Filling Material

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: **EndoREZ™ Points**

(Contd. of page 3)

At this time, the other constituents have no known exposure limits.

94-36-0 Benzoyl Peroxide

PEL Long-term value: 5 mg/m³

REL Long-term value: 5 mg/m³

TLV Long-term value: 5 mg/m³

108-88-3 Toluene

PEL Long-term value: 200 ppm
Ceiling limit value: 300; 500* ppm
*10-min peak per 8-hr shift

REL Short-term value: 560 mg/m³, 150 ppm
Long-term value: 375 mg/m³, 100 ppm

TLV Long-term value: 20 ppm
BEI, NIC-OTO

TWA Short-term value: 300 mg/m³, 100 ppm

· **Ingredients with biological limit values:****108-88-3 Toluene**

BEI 0.02 mg/L
Medium: blood
Time: prior to last shift of workweek
Parameter: Toluene

0.03 mg/L
Medium: urine
Time: end of shift
Parameter: Toluene

0.3 mg/g creatinine
Medium: urine
Time: end of shift
Parameter: o-Cresol with hydrolysis (background)

· **Additional information:** The lists that were valid during the creation 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.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 4)

Selection of the glove material is based 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

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Solid
Color:	According to product specification
Odor:	Characteristic
Odor threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined

- **Flash point:** Not applicable

- **Flammability (solid, gaseous):** Not determined.

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not applicable.

Density:	Not determined
Relative density	Not determined
Vapor density	Not applicable.
Evaporation rate	Not applicable.

- **Solubility in / Miscibility with**

Water: Insoluble.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 5)

· Solvent content:	
Organic solvents:	<10 %
VOC content:	0.92 %
· Solids content:	
	100.0 %
· 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** Strong acids, strong bases, and oxidizing agents.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:**
 - Zinc
 - Hydrocarbons
 - Carbon monoxide and carbon dioxide

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are 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)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 6)

· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

94-36-0	Benzoyl Peroxide	3
108-88-3	Toluene	3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

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.· **Behavior 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 (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 packagings:**· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number**· **DOT, ADN, IMDG, IATA**

Not Regulated

(Contd. on page 8)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: EndoREZ™ Points

(Contd. of page 7)

· **UN proper shipping name**
 · **DOT, ADN, IMDG, IATA** Not Regulated

· **Transport hazard class(es)**
 · **DOT, ADN, IMDG, IATA**
 · **Class** Not Regulated

· **Packing group**
 · **DOT, IMDG, IATA** Not Regulated

· **Environmental hazards:** Not Applicable.

· **Special precautions for user** Not Applicable

· **Transport in bulk according to Annex II of MARPOL 73/78 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**
 No further relevant information available.

· **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

94-36-0 Benzoyl Peroxide

108-88-3 Toluene

5124-30-1 Dicyclohexylmethane- 4,4' Diisocyanate

· **TSCA (Toxic Substances Control Act):**

94-36-0 Benzoyl Peroxide

ACTIVE

108-88-3 Toluene

ACTIVE

26570-48-9 Poly(ethylene glycol) Diacrylate

ACTIVE

162881-26-7 Organophosphine Oxide

ACTIVE

· **Hazardous Air Pollutants**

108-88-3 Toluene

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

108-88-3 Toluene

(Contd. on page 9)

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/05/2021

Reviewed on 06/03/2021

Trade name: **EndoREZ™ Points**

(Contd. of page 8)

· **Carcinogenic categories**· **EPA (Environmental Protection Agency)**

108-88-3	Toluene	II
----------	---------	----

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

94-36-0	Benzoyl Peroxide	A4
108-88-3	Toluene	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

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.

· **Department issuing SDS:** Environmental, Health, and Safety· **Contact:** Customer Service· **Date of preparation / last revision** 10/05/2021 / -· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

BEI: Biological Exposure Limit

Flam. Liq. 2: Flammable liquids – Category 2

Org. Perox. B: Organic peroxides – Type B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 2: Reproductive toxicity – Category 2

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