

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Trade Name: ***Pulpdent Root Canal Sealer***

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	<i>Pulpdent Root Canal Sealer Powder and Liquid</i>
1.2	Application / Use	Dental material for use by dental professional only.
1.2.2	SIC	851 Human health activity
1.2.3	Use Category	55
1.3	Manufacturer, Importer	
1.3.1	Manufacturer	<i>Pulpdent Corporation</i> 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative	International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcqc@globalnet.co.uk
2.0 Hazards Identification		
2.1	Classification	Irritant.
2.2	Adverse human health effects	May be irritating to eyes, respiratory system and skin. Do not inhale powder or vapor. May cause sensitization by inhalation or skin contact. Swallowing liquid may be harmful.
3.0 Composition		
3.1	Chemical characterization of the preparation:	Two-part, zinc oxide / eugenol dental cement. Powder and liquid are mixed together to initiate setting.

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	CAS Number	EC Number	Name of the Ingredient	Concentration	Warning symbol, R phrases
Powder	1314-13-2	215-222-5	Zinc oxide	40-60%	Xi (irritant); R36/37/38 Note: Zinc oxide which is not freshly formed, as in this product, is irritating but not harmful when inhaled
Liquid	97-53-0	202-589-1	Eugenol [2-Methoxy-4-(2-propenyl) phenol]	85-95%	Xi (irritant); R22, R36/37/38, R42/43

4.0 First Aid Measures

4.1	Special Instructions	Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Inhalation	Move to fresh air. If necessary, administer artificial respiration and seek medical attention.
4.3	Skin Contact	Wash skin thoroughly with soap and water.
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention if irritation persists.
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting except on the advice of physician. Get immediate medical attention. May be irritating to mucous membranes.
4.6	Further Information	Never give anything by mouth to an unconscious person.

5.0 Fire Fighting Measures

5.1	Suitable extinguishing media	Foam, carbon dioxide and dry chemical. Water spray may be used to keep fire exposed containers cool.
5.2	Extinguishing media to avoid	Do not use direct water stream
5.3	Special exposure hazards in a fire	Burning liberates carbon monoxide, carbon dioxide and smoke. As with all unsaturated fats and oils, some porous materials (rags, insulation, clay) when wetted with eugenol may undergo spontaneous combustion.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire fighting personnel. Cool exposed containers with water spray.

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6.0 Accidental Release Measures		
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat and safety glasses.
6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	<p>Powder should be carefully swept into dry, covered container. Avoid raising dust. Rinse area with water.</p> <p>Absorb Liquid with inert absorbent material (paper towels, etc.). Collect for disposal in a covered container kept in a cool place. Wash area of spill with detergent/soap and hot water. Rinse with hot water. Spills of Root Canal Liquid are very slippery.</p>
7.0 Handling and Storage		
7.1	Handling	For use only by dental professionals trained in their use. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap product immediately after use.
7.2	Storage	<p>Keep containers tightly closed. Store each part in original container at cool room temperature (<25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature.</p> <p>May darken with age. Shelf life of unopened liquid is three years from date of manufacture. Shelf life of the powder is five years from date of manufacture. Shelf life is dependent on proper storage conditions.</p>
7.3	Specific uses	Dental material for use in endodontic procedures.
8.0 Exposure Controls / Personal Protection		
8.1	Exposure limit values	<p>Zinc oxide: PEL: 5 mg/m³. TLV: 10 mg/m³.</p> <p>2-Methoxy-4-(2-propenyl) phenol: Not available</p>
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use of this product in the quantity provided.
8.2.1.1	Respiratory protection	None required. Good general ventilation is sufficient to control any nuisance dust or airborne vapors during normal conditions of use.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by

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dental staff.

- 8.2.1.4 Skin protection No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure.
- 8.2.1.5 Other controls Emergency eye wash fountain should be available. Wash hands after use.
- 8.2.2 Environmental exposure controls Powder is inert. Liquid should not be discharged into environment.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	<u>Powder</u>	<u>Liquid</u>
		Fine powder	Oily liquid
9.1.1	Color	White	Colorless to pale yellow
9.1.2	Odor	None	Cloves
9.2	Important health, safety and environmental information		
9.2.1	pH	Not applicable	7.0
9.2.2	Boiling point	Not applicable	253° C
9.2.3	Flash point	Not applicable	110° C
9.2.4	Flammability (solid, gas)	Not determined	Not applicable
9.2.5	Explosive properties	Not applicable	Not applicable
9.2.6	Oxidizing properties	Not determined	Not an oxygen donor
9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa	0.1 mm Hg
9.2.8	Specific gravity	5.650	1.064
9.2.9	Solubility in water	Nil	Slight
9.2.10	Partition coefficient	Not determined	Not determined
9.2.11	Viscosity	Not determined	Not determined
9.2.12	Vapor density	Not determined	Not determined
9.2.13	Evaporation rate	Not determined	Not determined

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10.0 Stability and reactivity		
10.1	Conditions to avoid	Heat (> 38°C), light, air.
10.2	Materials to avoid	Powder: Strong oxidizing agents. Liquid: Ferric chloride, Potassium permanganate.
10.3	Hazardous decomposition products	Carbon monoxide and carbon dioxide.
10.4	Further information	Eugenol is not pyrophoric, does not react with water, is not an oxygen donor and is shock stable.
11.0 Toxicological information		
11.1	Acute toxicity	Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.
11.2	Irritation and corrosiveness	Both powder and liquid may be irritating to eyes, respiratory system or skin on contact or with prolonged exposure.
11.3	Sensitization	Liquid may be sensitizing. Prolonged or frequent inhalation or skin contact may cause allergic reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged exposure to large amounts of zinc oxide may cause dermatitis unless good personal hygiene is practiced. Prolonged exposure to powder or liquid may cause eye and respiratory irritation.
11.5	Empirical data	Not available
11.6	Other information	None
12.0 Ecological Information		
12.1	Ecotoxicity	To the best of our knowledge, Root Canal Sealer Powder is inert. Root Canal Sealer Liquid should not be discharged into the environment.
13.0 Disposal Considerations		
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
14.0 Transport Information		
14.1	Restrictions	None. Not regulated.

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15.0 Regulatory Information	
15.1	Information on the warning label
15.1.1	Hazard symbol Xi
15.1.2	Hazardous ingredient Zinc oxide 2-Methoxy-4-(2-propenyl) phenol [<i>Eugenol</i>]
15.1.3	Risk phrases R22, Harmful if swallowed R36, Irritant to eyes. R37, Irritant to respiratory system. R38, Irritant to skin. R42/43, Sensitizing by inhalation or skin contact.
15.1.4	Safety phrases S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36: Wear suitable protective clothing. S39/49: Keep only in the original container in a cool, well ventilated place.
16.0 Other information	
16.1	List of relevant R phrases See above
16.2	Training advice Root Canal Sealer is for use only by dental professionals.
16.3	Restrictions on use Root Canal Sealer is for use only by dental professionals
16.4	Further information The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.5	Sources of key data National Institute for Occupational Safety (NIOSH) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised. This Safety Data Sheet has been revised to meet the requirements of Commission Directive 2001/58/EC.