

Safety Data SheetTrade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	Root Canal Sealer Powder and Liquid
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	
	Pulpdent Corporation	
	80 Oakland Street, P.O. Box 780	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262
	Watertown, MA 02472 USA	Email: Pulpdent@pulpdent.com
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
	UK Responsible Person	Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom
	CH Authorized Representative	MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland

2.0 Hazards Identification				
2.1	Classification			
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>
	<i>Powder</i>	Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
		Acute aquatic toxicity	1	H400
	<i>Liquid</i>	Eye irritation	2	H319
		STOT SE	3	H335
		Skin irritation	2	H315
		Skin sensitization	1	H317
		Respiratory sensitization	1	H334
		Harmful to aquatic life with long lasting effects.	3	H412
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	<i>Powder:</i> R 36/37/38-50/53 <i>Liquid:</i> R 36/37/38-42/43		

2.2 GHS Label Elements

Hazard Pictograms

Signal Word: **DANGER****Restricted to use by dental professional only.****Hazard Statements**

H315: Skin irritation. 2. May cause skin irritation.

H317: Sensitization. 1. May cause an allergic skin reaction.

H319: Eye irritation. 2. May cause eye irritation.

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H334: Respiratory sensitization. 1. May cause allergy or asthma symptoms.

H335: STOT SE. 3. May cause respiratory irritation.

H400: Very toxic to aquatic life.

H412: Harmful to aquatic life with long lasting effects.

Precautionary Statements

P261: Avoid breathing dust/vapor/fume/gas/mist/spray.

P273: Avoid release to the environment.

P280: Wear protective gloves and eye protection

P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

P333+P313: If irritation or rash occurs, get medical advice/attention.

3.0 Composition

3.1 Chemical characterization of the preparation: Two-part, zinc oxide / eugenol dental cement

3.2 Hazardous ingredients

	CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1272/2008 (CLP).
Powder	1314-13-2	Zinc oxide	40-60%	Irritant, Xi R 36/37/38-50/53	Eye irritation, 2 STOT SE 3 Skin irritation, 2 Acute aquatic toxicity, 1
Liquid	97-53-0	Eugenol [2-Methoxy-4-(2-propenyl) phenol]	85-95%	Irritant; Xi, R 36/37/38-42/43	Eye irritation, 2 STOT SE 3 Skin irritation, 2 Skin sensitization, 1 Respiratory sensitization, 1 Harmful to aquatic life with long lasting effects, 3

4.0 First Aid Measures

4.1	General Information	May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Liquid may cause sensitization by skin contact or inhalation. 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 oxygen / artificial respiration and seek medical attention.
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap / water.
4.4	Eye Contact	Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes.
4.6	Precautions for first responders	Ventilate the area. Wear eye and skin protection.
4.7	Information for physicians	
	Symptoms	Irritation/redness in eyes, throat or on skin. Allergy or asthma symptoms
	Hazards	May be irritating to eyes, respiratory system and skin. May cause sensitization by skin contact or inhalation.

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Treatment		As above under First Aid.
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	Self-contained breathing apparatus.
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	Powder: Carefully sweep into dry, covered container. Avoid raising dust. Rinse area with water. Liquid: Absorb or wipe up spill with inert, absorbent material (paper towels or cloths). Collect for disposal in a covered container kept in a cool place. Wash area of spill with soap and water. Spills of Root Canal Liquid leave surfaces very slippery.
7.0	Handling and Storage	
7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Cap powder / liquid immediately after use. Avoid cross-contamination.
7.2	Storage	Store tightly capped in original containers at cool room temperature (<25°C). Avoid direct, strong light, ignition sources, temperature extremes (>27°C/80°F, <5°C/40°F). Provided that the material has been stored properly, shelf life for unopened powder is 5 years from date of manufacture; shelf life for unopened liquid is 3 years.
7.3	Specific uses	Professional dental material
8.0	Exposure Controls / Personal Protection	
8.1	Exposure limit values	Zinc oxide: PEL: 5 mg/m ³ . TLV: 10 mg/m ³ . Eugenol: Not established
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment required under normal conditions of use.
8.2.1.1	Respiratory protection	Good general ventilation is sufficient to control any nuisance dust or airborne vapors.
8.2.1.2	Hand protection	Usual surgical gloves worn by dental staff will limit contact with material.
8.2.1.3	Eye protection	Usual safety glasses worn by dental staff.
8.2.1.4	Skin protection	Good personal hygiene and safety practices and wearing a lab coat.
8.2.1.5	Other controls	Emergency eye wash fountain close-by. Wash hands after use.
8.2.2	Environmental exposure controls	Neither powder nor liquid should be discharged into environment.

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9.0	Physical and Chemical Properties		
9.1	Characteristics	<u>Powder</u>	<u>Liquid</u>
9.1.1	Appearance / Physical state / Color	Fine white powder	Colorless to pale yellow oily liquid
9.1.2	Odor	None	Oil of 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	112°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
10.0	Stability and reactivity		
10.1	Conditions to avoid	Temperature > 38°C, light, air, cross-contamination.	
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	Minimal health hazard in the quantities present in this product and under normal conditions of use. Zinc oxide: TWA: 5 mg/m³ Eugenol: Oral LD ₅₀ rat – 1930 mg/kg	
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/frequent inhalation or skin contact may cause allergic reactions in 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/liquid may cause eye/respiratory irritation.	
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known	

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11.6	Empirical data	Not available
11.7	Clinical experience	Zinc oxide / eugenol cements have been used safely and effectively in dental procedures for more than 70 years.
12.0 Ecological Information		
12.1	Ecotoxicity	Root Canal Sealer powder and Liquid should not be discharged into the environment. Both zinc oxide and eugenol are harmful to aquatic life.
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	Not regulated
15.0 Regulatory Information		
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device.
15.3	Health Canada	Class III medical device
16.0 Other information		
16.1	List of relevant R phrases	R 36/37/38, Irritating to eyes, respiratory system and skin. R 42/43, May be sensitizing by inhalation or skin contact. R 50/53, Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
16.2	Hazard Statements	H319: Eye irritation. 2. May cause eye irritation. H335: STOT SE. 3. May cause respiratory irritation. H315: Skin irritation. 2. May cause skin irritation. H317: Sensitization. 1. May cause an allergic skin reaction. H334: Respiratory sensitization. 1. May cause allergy or asthma symptoms. H400: Very toxic to aquatic life. 1 H412: Harmful to aquatic life with long lasting effects. 3
16.3	Precautionary Statements	P261: Avoid breathing vapor. P273: Avoid release to the environment. P280: Wear protective gloves and eye protection P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician. P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. P337+P313: If eye irritation persists, get medical advice/attention. P302+P352: If on skin, wash with plenty of soap and water. P333+P313: If irritation or rash occurs, get medical advice/attention.
16.4	Restrictions on use	For professional use only.

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16.5	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) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the GHS SDS format and the requirements of Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.
