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
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

Telephone: 07989 407479 / Fax: 01256 350330
Email: s.williams5@btconnect.com

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP] Powder
Hazard Class Hazard Category Hazard Statement
Eye irritation 2 H319
STOT SE 3 H335
Skin irritation 2 H315

Liquid
Eye irritation 2 H319
STOT SE 3 H335
Skin irritation 2 H315
Skin sensitization 1 H317
Respiratory sensitization 1 H334

2.1.2 Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) Irritant; Xi; Powder: R 36/37/38
Liquid: 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
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.

Precautionary Statements
P261: Avoid breathing vapor.
P280: Wear protective gloves and eye protection
P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician.
P305+P351: If in eyes, rinse cautiously with water for several minutes.
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

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the Ingredient</th>
<th>Concentration</th>
<th>Classification according to 67/548/EEC</th>
<th>Classification according to Regulation (EC) No.1278/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powder</td>
<td>Zinc oxide</td>
<td>40-60%</td>
<td>Irritant; Xi, R 3637/38</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td>
</tr>
<tr>
<td>Liquid</td>
<td>Eugenol [2-Methoxy-4-(2-propenyl) phenol]</td>
<td>85-95%</td>
<td>Irritant; Xi, R 36/37/38-42/43</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Respiratory sensitization, 1, H334</td>
</tr>
</tbody>
</table>

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 and water for 15 minutes.

4.4 Eye Contact
Keep eyelids apart and 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 or 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.

### 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
A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray.

## 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. Do not smoke, eat or drink while using. Cap powder and liquid immediately after use. Avoid cross-contamination of parts.

### 7.2 Storage
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 (>27°C/80°F, <5°C/40°F). Provided that the material has been stored properly, shelf life for unopened powder is five years from date of manufacture; shelf life for unopened liquid is three years from date of manufacture.

### 7.3 Specific uses
Professional dental material
## 8.1 Exposure limit values
Zinc oxide: PEL: 5 mg/m³. TLV: 10 mg/m³.
Eugenol: Not established

### 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
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 should protect dental staff from unnecessary exposure to material.

#### 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

<table>
<thead>
<tr>
<th>9.1</th>
<th>Appearance / Color</th>
<th>Powder</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Fine powder</td>
<td>Oily liquid</td>
</tr>
<tr>
<td>9.1.1</td>
<td>Color</td>
<td>White</td>
<td>Colorless to pale yellow</td>
</tr>
<tr>
<td>9.1.2</td>
<td>Odor</td>
<td>None</td>
<td>Cloves</td>
</tr>
</tbody>
</table>

### 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

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Pulpdent Corporation
Safety Data Sheet
Trade Name: PULPDENT ROOT CANAL SEALER POWDER AND LIQUID

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
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 Carcinogenicity, Mutagenicity, Reproductive Toxicity
None known

11.6 Empirical data
Not available

11.7 Clinical experience
Zinc oxide/eugenol cements, like Root Canal Sealer, have been used successfully in dental procedures for more than 70 years. They are considered to be safe and effective treatment.

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. No other information is available.

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.

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
- R36/37/38, Irritating to eyes, respiratory system and skin.
- R42/43, May be sensitizing by inhalation or skin contact.

16.2 Hazard Statements
- H319: Eye irritation. 2. May cause eye irritation.
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- H315: Skin irritation. 2. May cause skin irritation.
- H317: Sensitization. 1. May cause an allergic skin reaction.
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16.3 Precautionary Statements
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- 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
Root Canal Sealer is to be sold to and used by dental professionals only.

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)

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.