

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

075906789

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

075906763

**MATERIAL SAFETY DATA SHEET: EUGENOL & EUGENOL-BASED PRODUCTS**

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**IDENTITY:**

Trade Name:

Root Canal Sealer Liquid  
Eugenol

Code:

RSL, RSL-2  
E-02, E-04, E-16

Chemical Description: 2-Methoxy-4-(2-propenyl) phenol  
Product use: Dental cement component

**SECTION I**

Pulpdent Corporation  
80 Oakland Street  
Watertown, MA 02472 USA

Phone Numbers:  
24 Hour Emergency: 1-800-535-5053  
Customer Service: 1-800-343-4342 / 1-617-926-6666

Date prepared: September 1, 2008

**SECTION II - HAZARDOUS INGREDIENTS**

Ingredients

CAS Number

PEL/TLV

2-Methoxy-4-(2-propenyl) phenol

97-53-0

Not established

DOT HAZARD CLASSIFICATION: Non-hazardous

WHMIS CLASSIFICATION: D-2 (Irritation possible)

NFPA HMIS RATING: HEALTH: 2

FLAMMABILITY: 1

REACTIVITY: 0

**SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS**

Boiling Point: 253°C

Specific Gravity: 1.067

Vapor Pressure: 0.01

Melting Point: -7.5°C

Vapor Density: >1.0

Solubility in water: Negligible

Odor Threshold: Not available

Appearance and Odor: Slightly yellow, oily liquid with clove odor

**SECTION IV - FIRE AND EXPLOSION HAZARD DATA**

Flash Point: > 93°C (Closed Cup)

Flammable limits: Not established

Extinguishing Media: Water, foam, CO<sub>2</sub> and dry chemical.

Special Fire Fighting Procedures: Use standard procedures.

Hazardous Combustion Products: Burning liberates carbon monoxide, carbon dioxide and smoke.

**SECTION V - REACTIVITY DATA**

Stability: Stable, even at elevated temperatures.

Conditions to avoid: None

Incompatibility: Avoid strong oxidizing agents.

Hazardous Decomposition Products: None

Hazardous Polymerization: Does not occur

Conditions to avoid: None

**MATERIAL SAFETY DATA SHEET: EUGENOL & EUGENOL-BASED PRODUCTS**

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**SECTION VI - HEALTH HAZARD DATA**

*Summary of Acute Hazards:* Minimal health hazard. May be irritating to skin or eyes.

| <i>Route of Exposure</i> | <i>Signs &amp; Symptoms</i>                                                     |
|--------------------------|---------------------------------------------------------------------------------|
| Inhalation               | None                                                                            |
| Eye Contact              | May be irritating.                                                              |
| Skin absorption          | Not applicable                                                                  |
| Skin Contact             | May be irritating. Prolonged or repeated contact may cause allergic dermatitis. |
| Ingestion                | May be irritating to mucous membranes. LD <sub>50</sub> (oral rat): 2g / kg     |

*Summary of Chronic Hazards:* Prolonged/repeated skin contact may cause allergic dermatitis. Repeated ingestion of large amounts may cause liver damage.

|                       |                  |
|-----------------------|------------------|
| Carcinogenicity       | Not a carcinogen |
| Teratogenicity        | None known       |
| Mutagenicity          | None known       |
| Reproductive Toxicity | None known       |

*Emergency First Aid Procedures:*

|              |                                                                                                                   |
|--------------|-------------------------------------------------------------------------------------------------------------------|
| Inhalation   | Not applicable                                                                                                    |
| Eye contact  | Irrigate with water for 15+ minutes; seek medical care for persistent irritation.                                 |
| Ingestion    | Rinse mouth with water. Give milk or water to dilute. Seek emergency medical attention.                           |
| Skin contact | Remove contaminated clothes. Wash affected area with soap and water. If irritation persists, seek medical advice. |

**SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE**

*Handling and Storage Precautions:* Keep away from heat and flame. Keep container closed when not in use. Use with adequate ventilation.

*Steps to Be Taken if Material is Released or Spilled:* Small spills can be wiped up with cloth, paper, or standard absorbents (sand, sawdust, vermiculite, etc.) and placed in covered container. Wash area of spill.

*Waste Disposal Method:* Dispose of waste according to government regulations.

*Other Precautions:* Use good laboratory hygiene, i.e., no eating, drinking or smoking during use.

**SECTION VIII - CONTROL MEASURES**

*Respiratory Protection:* None required.

*Ventilation:* No special ventilation recommended under anticipated conditions of normal use.

*Protective Gloves:* Oil resistant gloves recommended.

*Eye Protection:* Splash-resistant safety glasses

*Other Protective Clothing or Equipment:* Emergency eye wash fountain should be close by and maintained.

*Work/Hygienic Practices:* Wash hands after use.

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**MATERIAL SAFETY DATA SHEET: EUGENOL & EUGENOL-BASED PRODUCTS**

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**Ingredients**

**CAS Number**

**PEL/TLV**

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DOT HAZARD CLASSIFICATION: Non-hazardous

WHMIS CLASSIFICATION: D-2 (Irritation possible)

NFPA HMIS RATING: HEALTH: 2

FLAMMABILITY: 1

REACTIVITY: 0

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Boiling Point: 253°C

Specific Gravity: 1.067

Vapor Pressure: 0.01

Melting Point: -7.5°C

Vapor Density: >1.0

Solubility in water: Negligible

Odor Threshold: Not available

Appearance and Odor: Slightly yellow, oily liquid with clove odor

**SECTION IV - FIRE AND EXPLOSION HAZARD DATA**

Flash Point: > 93°C (Closed Cup)

Flammable limits: Not established

Extinguishing Media: Water, foam, CO<sub>2</sub> and dry chemical.

Special Fire Fighting Procedures: Use standard procedures.

Hazardous Combustion Products: Burning liberates carbon monoxide, carbon dioxide and smoke.

**SECTION V - REACTIVITY DATA**

Stability: Stable, even at elevated temperatures.

Conditions to avoid: None

Incompatibility: Avoid strong oxidizing agents.

Hazardous Decomposition Products: None

Hazardous Polymerization: Does not occur

Conditions to avoid: None

**MATERIAL SAFETY DATA SHEET: EUGENOL & EUGENOL-BASED PRODUCTS**

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**SECTION VI - HEALTH HAZARD DATA**

*Summary of Acute Hazards:* Minimal health hazard. May be irritating to skin or eyes.

| <i>Route of Exposure</i> | <i>Signs &amp; Symptoms</i>                                                     |
|--------------------------|---------------------------------------------------------------------------------|
| Inhalation               | None                                                                            |
| Eye Contact              | May be irritating.                                                              |
| Skin absorption          | Not applicable                                                                  |
| Skin Contact             | May be irritating. Prolonged or repeated contact may cause allergic dermatitis. |
| Ingestion                | May be irritating to mucous membranes. LD <sub>50</sub> (oral rat): 2g / kg     |

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|                       |                  |
|-----------------------|------------------|
| Carcinogenicity       | Not a carcinogen |
| Teratogenicity        | None known       |
| Mutagenicity          | None known       |
| Reproductive Toxicity | None known       |

*Emergency First Aid Procedures:*

|              |                                                                                                                   |
|--------------|-------------------------------------------------------------------------------------------------------------------|
| Inhalation   | Not applicable                                                                                                    |
| Eye contact  | Irrigate with water for 15+ minutes; seek medical care for persistent irritation.                                 |
| Ingestion    | Rinse mouth with water. Give milk or water to dilute. Seek emergency medical attention.                           |
| Skin contact | Remove contaminated clothes. Wash affected area with soap and water. If irritation persists, seek medical advice. |

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*Waste Disposal Method:* Dispose of waste according to government regulations.

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**SECTION VIII - CONTROL MEASURES**

*Respiratory Protection:* None required.

*Ventilation:* No special ventilation recommended under anticipated conditions of normal use.

*Protective Gloves:* Oil resistant gloves recommended.

*Eye Protection:* Splash-resistant safety glasses

*Other Protective Clothing or Equipment:* Emergency eye wash fountain should be close by and maintained.

*Work/Hygienic Practices:* Wash hands after use.

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

| <b>1.0 Commercial Product Name and Supplier</b> |                                                                                                           |                                                                                                                            |
|-------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| 1.1                                             | Commercial product name / designation                                                                     | <b>Root Canal Sealer Powder and Liquid</b>                                                                                 |
| 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<br><b>Pulpdent Corporation</b><br>80 Oakland Street, P.O. Box 780<br>Watertown, MA 02472 USA | Telephone: 1 617 926-6666 / Fax: 1 617 926-6262<br>Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a> |
| 1.4                                             | Emergency Telephone Number                                                                                | 1-800-535-5053 (24 Hour / USA)                                                                                             |
| 1.5                                             | Authorized European Representative                                                                        | Advena Ltd.<br>Pure Offices, Plato Close<br>Warwick, CV34 6WE<br>United Kingdom                                            |

| <b>2.0 Hazards Identification</b> |                                                                                                    |                                                                    |                        |                         |
|-----------------------------------|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------|-------------------------|
| 2.1                               | Classification                                                                                     |                                                                    |                        |                         |
| 2.1.1                             | Classification according to Regulation (EC)<br>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<br>(See SECTION 16 for full text of risk phrases) | <i>Powder:</i> R 36/37/38-50/53<br><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.

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.

**Safety Data Sheet**Trade Name: **PULPDENT ROOT CANAL SEALER POWDER AND LIQUID****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.

| <b>3.0 Composition</b>        |                                                                                            |                                              |                                                                                                                                                                                                                                             |                                        |                                                                                                                                                                       |
|-------------------------------|--------------------------------------------------------------------------------------------|----------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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<br>R 36/37/38-50/53       | Eye irritation, 2<br>STOT SE 3<br>Skin irritation, 2<br>Acute aquatic toxicity, 1                                                                                     |
| Liquid                        | 97-53-0                                                                                    | Eugenol<br>[2-Methoxy-4-(2-propenyl) phenol] | 85-95%                                                                                                                                                                                                                                      | Irritant; Xi,<br>R 36/37/38-42/43      | Eye irritation, 2<br>STOT SE 3<br>Skin irritation, 2<br>Skin sensitization, 1<br>Respiratory sensitization, 1<br>Harmful to aquatic life with long lasting effects, 3 |
| <b>4.0 First Aid Measures</b> |                                                                                            |                                              |                                                                                                                                                                                                                                             |                                        |                                                                                                                                                                       |
| 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.                                                                                                                              |                                        |                                                                                                                                                                       |
|                               | Treatment                                                                                  |                                              | As above under First Aid.                                                                                                                                                                                                                   |                                        |                                                                                                                                                                       |

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

|                                                    |                                                |                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>5.0 Fire Fighting Measures</b>                  |                                                |                                                                                                                                                                                                                                                                                                                                                                     |
| 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.                                                                                                                                                                                                                                                                                                                                 |
| <b>6.0 Accidental Release Measures</b>             |                                                |                                                                                                                                                                                                                                                                                                                                                                     |
| 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.<br><br>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. |
| <b>7.0 Handling and Storage</b>                    |                                                |                                                                                                                                                                                                                                                                                                                                                                     |
| 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                                                                                                                                                                                                                                                                                                                                        |
| <b>8.0 Exposure Controls / Personal Protection</b> |                                                |                                                                                                                                                                                                                                                                                                                                                                     |
| 8.1                                                | Exposure limit values                          | Zinc oxide: PEL: 5 mg/m <sup>3</sup> . TLV: 10 mg/m <sup>3</sup> .<br>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.                                                                                                                                                                                                                                                                                                    |



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

| 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.<br>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.<br>Zinc oxide: TWA: 5 mg/m³<br>Eugenol: Oral LD <sub>50</sub> 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. |                                      |

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

|             |                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------|------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 11.5        | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>12.0</b> | <b>Ecological Information</b>                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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.                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>13.0</b> | <b>Disposal Considerations</b>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 13.1        | Regulations                                          | Follow all local and national government regulations in disposing material or contaminated packaging.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>14.0</b> | <b>Transport Information</b>                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 14.1        | Restrictions                                         | Not regulated                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>15.0</b> | <b>Regulatory Information</b>                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>16.0</b> | <b>Other information</b>                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 16.1        | List of relevant R phrases                           | R 36/37/38, Irritating to eyes, respiratory system and skin.<br>R 42/43, May be sensitizing by inhalation or skin contact.<br>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.<br>H335: STOT SE. 3. May cause respiratory irritation.<br>H315: Skin irritation. 2. May cause skin irritation.<br>H317: Sensitization. 1. May cause an allergic skin reaction.<br>H334: Respiratory sensitization. 1. May cause allergy or asthma symptoms.<br>H400: Very toxic to aquatic life. 1<br>H412: Harmful to aquatic life with long lasting effects. 3                                                                                                                                                                             |
| 16.3        | Precautionary Statements                             | P261: Avoid breathing vapor.<br>P273: Avoid release to the environment.<br>P280: Wear protective gloves and eye protection<br>P342+P311: If experiencing respiratory symptoms, call a poison center or doctor/physician.<br>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.<br>P337+P313: If eye irritation persists, get medical advice/attention.<br>P302+P352: If on skin, wash with plenty of soap and water.<br>P333+P313: If irritation or rash occurs, get medical advice/attention. |
| 16.4        | Restrictions on use                                  | For professional use only.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

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

|      |                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|------|-------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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)<br>US Occupational Safety and Health Administration (OSHA)<br>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).<br>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.                                                                                                                                                                                            |

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