# **SAFETY DATA SHEETS**

This SDS packet was issued with item: 078579424

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

076654818 078910409

# Material Safety Data Sheet

Sultan Healthcare 85 West Forest Avenue, Englewood, NJ 07631 Phone: 201-871-1232 • Toll Free: 800-637-8582 Fax: 201-871-0321 • http://sultanhealthcare.com EU Auth. Rep. (MDD 93/42/EEC) MDSS GmbH · Schiffgraben 41 · D-30175 Hannover, Germany

FOR CHEMICAL EMERGENCY: CALL INFOTRAC 1-800-535-5053 24 Hrs. per day, 7 days per week Outside the United States call collect 1-352-323-3500

Date Reviewed: May 19, 2008

- 1. Chemical Identification Common Name: Eugenol, USP Ref #: 10511 (1/2 oz) 10502 (1 oz), 10504 (4 oz), 10505 (8 oz), 10506 (16 oz) & 10507 (1 gal)
- 2. Composition/Information on Ingredients Eugenol USP CAS # 97-53-0 Percent: 100 %

#### 3. Hazards Identification

This material is an aromatic chemical. Eugenol is irritating to the eyes. Repeated contact may cause allergic dermatitis. Swallowing may cause severe tissue damage.

#### 4. First Aid Measures

Eye Contact: Wash eyes by normal first aid methods. Skin Contact: Wash with soap and cold water. Inhalation: Remove person to well ventilated area. Ingestion: Seek medical attention immediately.

#### 5. Fire Fighting Measures

Flash Point and Method: 252 F, closed cup Extinguishing Media: Carbon dioxide, dry chemical or foam

Special Fire Fighting Procedures: Cool containers exposed to flame with water

Unusual Fire and Explosion Hazards: N/A

- 6. Accidental Release Measures Wipe small spills with paper and place into a metal waste container. For large spills, use non-flammable absorbent.
- 7. Handling and Storage Store in tightly sealed containers in cool dry area. Do not expose to temperatures above 35 C.
- 8. Exposure Controls/Personal Protection Respiratory Protection: Avoid casual breathing Eye Protection: Use OSHA approved Safety Glasses Exhaust Required: Local exhaust recommended (explosion proof) Skin: Protective Gloves

Special Protective Clothing: Follow good industrial practice

9. Physical and Chemical Properties Appearance: Colorless to pale yellow oily liquid which darkens and thickens when exposed to air. Odor: Cloves; pungent and spicy taste Solubility in Water: Insoluble Boiling Point (° C): 254 Melting Point (° C): - 9 Vapor Pressure (mm Hg @ 20 C): 0.009 Specific Gravity ( $H_2O = 1$ ): 1.064 @ 25 C

#### 10. Stability and Reactivity Stability: Stable Materials to Avoid: Strong oxidizing agents Hazardous Polymerization: Will not occur Hazardous Decomposition Products: Dioxide upon burning Conditions to Avoid: Excessive heat

Q-Form 10-111, Rev. D \*\*\*\*\*

- 11. Toxicological Information: LD<sub>50</sub> orally in rats: 2680 mg/kg
- 12. Ecological Information No data available
- 13. Disposal Considerations: Dispose of in accordance with all local, state, and federal regulations.
- 14. Transit Information Not DOT regulated

#### 15. Regulatory Information

This mixture contains the following toxic chemicals subject to the reporting requirements of Section 313 of Title III of Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

#### 16. Other Information:

The information contained herein is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data or the results to be obtained from the use there of. In no event will the manufacturer or the distributor be responsible for damages of any nature whatsoever resulting from the use of or reliance upon this information. General properties are to be regarded as guidelines and are not guaranteed for all samples.

Eugenol



# Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 22 June 2009 Document Number: 10504MS Date Revised: 24 June 2016 Revision Number: 4

| I. PRODUCT IDENTIFICATION                |  |  |  |
|--|--|--|--|
| Trade Name (as labeled):                 | Eugenol, U.S.P.                                    |  |  |
| Chemical Name/Classification:            | Eugenol  |  |  |
| Product Identifier (Part/Item Number):   | 10504  |  |  |
| U.N. Number:                             | None   |  |  |
| U.N. Dangerous Goods Classification:     | None   |  |  |
| Recommended Use:                         | Local antiseptic for root canals                   |  |  |
| Restrictions on Use:                     | Professional use only                              |  |  |
| Manufacturer/Supplier Name:              | Sultan Healthcare                                  |  |  |
| Manufacturer/Supplier Address:           | 1301 Smile Way                                     |  |  |
|  | York, PA 17404                                     |  |  |
| Manufacturer/Supplier Telephone Number:  | 800-989-8826 or 717-767-8502 (Product Information) |  |  |
| Transportation Emergency Contact Number: | 800-424-9300 Chemtrec                              |  |  |
| E-Mail Address:                          | <u>customer.service@sultanhc.com</u>               |  |  |

# **1. PRODUCT IDENTIFICATION**

# 2. HAZARD(s) IDENTIFICATION

## Hazard/Danger Classification (Regulation EC) No. 1272/2008 [CLP]:

| Health  | Environmental | Physical |
|---|---------------|----------|
| Skin Irritation Category 2<br>Acute Toxicity Category 4 (H302)<br>Skin Sensitization Category 1 | None          | None     |

EU Classification (67/548/EEC as amended): Irritant (Xi), Harmful (Xn)

**EU Risk (R) and Safety (S) Phrases:** R22, R38, R43, S24, S37, S28

## Refer to Section 16 for the full text of the EU Classifications and R Phrases.

Eugenol, U.S.P.

## Label Elements:

## Signal Word: WARNING!

| Hazard Statements   |   | Precautionary Statements  |
|---|---|---|
| Contains Eugenol<br>H302 Harmful if swallowed.<br>H315 Causes skin irritation.<br>H317 May cause an allergic skin reaction. | P261<br>P264<br>P270<br>P272<br>P280<br>P301 + P312<br>P330<br>P302 + P352<br>P333 + P313<br>P362<br>P501 | Avoid breathing mist/vapours/spray.<br>Wash thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Contaminated work clothing should not be allowed out of the<br>workplace.<br>Wear protective gloves.<br>IF SWALLOWED: Call a POISON CENTER or doctor/physician if<br>you feel unwell.<br>Rinse mouth.<br>IF ON SKIN: Wash with plenty of soap and water.<br>If skin irritation or rash occurs: Get medical advice/attention.<br>Take off contaminated clothing and wash before reuse.<br>Dispose of contents/container in accordance with local and national<br>regulations. |

# 3. COMPOSITION AND INFORMATION ON INGREDIENTS

| Hazardous Components | C.A.S. #<br>EC#     | IUPAC Name                    | WT % |
|----------------------|---------------------|-------------------------------|------|
| Eugenol              | 97-53-0 / 202-589-1 | 2-methoxy-4-prop-2-enylphenol | 100  |

## 4. FIRST-AID MEASURES

| Routes of<br>Exposure                        | First Aid Instructions  |
|--|---|
| Eye  | Immediately flush eyes with large quantities of water, holding the eyelids apart. Get medical attention if irritation persists.   |
| Skin   | Wash with soap and water. If irritation or rash develops, discontinue use and get medical advice.   |
| Inhalation                                   | None needed under normal use conditions.  |
| Ingestion                                    | If swallowed, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to or induce vomiting in an unconscious or convulsing person. Get medical attention. |
| Most Important<br>Symptoms of<br>Exposure    | May cause mild eye irritation. May cause skin irritation. May cause sensitization by skin contact.<br>Harmful if swallowed.   |
| Other  | Eugenol has been shown to inhibit peripheral sensory nerve activity in low doses. At higher doses, it can produce neurotoxicity.  |
| Note to Physicians (<br>of symptoms and clin | (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control nical conditions.   |

# 5. FIRE-FIGHTING MEASURES

| Suitable Extinguishing Media:               | Use water spray, dry chemical, halon, or carbon dioxide to extinguish a fire.   |
|---|---|
| Fire Fighting Procedures:                   | Cool fire exposed containers and structures with water.   |
| Specific Hazards Arising from the Chemical: | This product is not flammable but will burn under fire condition. Combustion may produce oxide of carbon.                                     |
| Precautions for Fire Fighters:              | Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals. |

| <b>Recommended Protective Equipment for Fire Fighters:</b> |      |             |         |
|--|------|-------------|---------|
| EYES/FACE  | SKIN | RESPIRATORY | THERMAL |
| R  |      |             |         |

# 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, PPE and Emergency Procedures:** For large spills, wear eye protection. Eliminate all sources of ignition. Ventilate the area. Small spills do not require special precautions.

**Environmental Precautions:** Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and Materials for Containment and Clean-Up: Collect using an inert non-combustible absorbent material and place in appropriate containers.

| Recommended Personal Protective Equipment for Containment and Clean-up: |      |             |         |
|---|------|-------------|---------|
| EYES/FACE   | SKIN | RESPIRATORY | THERMAL |
| $\overline{\bigcirc}$   |      |             |         |

## 7. HANDLING AND STORAGE

**Precautions for Safe Handing:** Avoid contact with eyes, skin and clothing. Avoid breathing vapors. Use with adequate ventilation. Wash exposed skin thoroughly with soap and water after use.

Empty containers retain product residue. Follow all precautions in SDS when handling empty containers.

**Conditions for Safe Storage:** Store in a cool, dry, well ventilated area away from incompatible materials. Protect from physical damage. Do not expose to temperatures above 95°F (35°C).

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### **Occupational Exposure Limits:**

| Eugenol | United States  | None Established |
|---------|----------------|------------------|
| 0       | Germany        | None Established |
|         | United Kingdom | None Established |
|         | France         | None Established |
|         | Spain          | None Established |
|         | Italy          | None Established |
|         | European Union | None Established |

Biological Exposure Limits: None Established

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposure levels.

## Individual Protection Measures (PPE)

Specific Eye/Face Protection: Chemical safety goggles recommended if splashing is possible.

**Specific Skin Protection:** Wear impervious gloves such as butyl or nitrile. Recommended Glove: butyl or nitrile. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None required under normal use conditions.

Specific Thermal Hazards: Not applicable.

|                              | <b>Recommended Persona</b>  | l Protective Equipment: |         |
|------------------------------|-----------------------------|-------------------------|---------|
| EYES/FACE                    | SKIN                        | RESPIRATORY             | THERMAL |
| $\bigcirc$                   |                             |                         |         |
| Environmental Exposure Contr | ols: None required for norm | al use conditions.      |         |
|                              |                             |                         |         |

**General Hygiene Considerations and Work Practices:** Avoid contact with the eyes, skin and clothing. Avoid breathing vapors or mists. Wash thoroughly with soap and water after handling.

**Protective Measures During Repair and Maintenance of Contaminated Equipment:** Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling.

| Appearance:                         | Colorless to pale yellow liquid | Explosive Limits:                           | Not applicable |
|-------------------------------------|---------------------------------|---|----------------|
| Odor:                               | Pungent, spicy                  | Vapor Pressure<br>(mmHg @ 20°C):            | 0.009          |
| Odor Threshold:                     | Not available                   | Vapor Density:                              | Not available  |
| рН:                                 | Not available                   | Specific Gravity:<br>(H <sub>2</sub> O = 1) | 1.066 @ 20°C   |
| Melting/Freezing<br>Point:          | 15.4°F (-9.2°C)                 | Solubility:                                 | Insoluble      |
| Initial Boiling Point<br>and Range: | 491°F (255°C)                   | Partition Coefficient:<br>n-octanol/water:  | 2.27 log Kow   |
| Flash Point:                        | 485.6°F (252°C)                 | Auto-Ignition<br>Temperature:               | Not available  |
| Evaporation Rate:                   | Not available                   | Decomposition<br>Temperature:               | Not available  |
| Flammability:                       | Not flammable                   | Viscosity:                                  | Not available  |
| Explosive Properties:               | None                            | Oxidizing Properties:                       | None           |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

## **10. STABILITY AND REACTIVITY**

**Reactivity:** Will not react under normal use conditions.

Chemical Stability: Stable under normal use conditions.

Possibility of Hazardous Reactions: Not reactive under normal conditions of use.

Conditions to Avoid: Exposure to air may cause the liquid to darken and thicken.

Incompatible materials: Avoid oxidizing agents, strong alkalies, iron and zinc.

Hazardous Decomposition Products: Thermal decomposition may produce carbon monoxide and carbon dioxide.

Eugenol, U.S.P.

# **11. TOXICOLOGICAL INFORMATION**

## Potential Health Effects:

Eyes: May cause mild irritation with redness and tearing.

Skin: May cause skin irritation. May cause anesthetic effects. Studies in humans show that eugenol causes contact dermatitis.

<u>Ingestion</u>: Swallowing may cause gastrointestinal irritation, nausea, vomiting, diarrhea, weakness, lethargy and ataxia. Inhalation: Inhalation exposure will not occur in normal use.

<u>Chronic Health Effects</u>: Prolonged overexposure to eugenol may cause damage the kidneys, liver and adrenal glands.

<u>Carcinogenicity</u>: None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

There was no evidence of carcinogenicity observed for male or female rats. For mice there was equivocal evidence of carcinogenicity since eugenol caused increase incidences of both carcinomas and adenomas of the liver in male mice at the 3,000 ppm dietary level. Eugenol was associated with an increase in the combined incidences of hepatocellular carcinomas or adenomas in female mice.

<u>Mutagenicity</u>: Eugenol was negative in the AMES test, positive in a mouse lymphoma assay, both positive and negative results were found in a in vitro CHO assay and negative in a in vivo mouse micronucleus assay.

Medical Conditions Aggravated by Exposure: May aggravate existing skin conditions.

Acute Toxicity Data: LD50 Rat oral 1930mg/kg

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):

<u>Single Exposure</u>: Eugenol has been shown to inhibit peripheral sensory nerve activity in low doses. In high doses, it can produce neurotoxicity.

<u>Repeated Exposure</u>: In a 4 month study, rats given 1% of their diet showed no liver damage. In another study, rats were given 0.1-1% for 19 weeks showed no changes in growth, hematology, organ weights and histology In a 34 days oral study, rats were given 1.4 grams increasing to 4 grams of eugenol over 34 days. Enlargement of the liver and adrenals, hyperplasia and hyperkeratosis of the skin with focal ulcerations.

# **12. ECOLOGICAL INFORMATION**

Toxicity: 96 hr LC50 Pimephales promelas (Fathead minnow) 24 mg/L

Persistence and Degradability: No data is available.

**Bio-accumulative Potential:** The potential for bioconcentration in aquatic organisms is moderate, provided the compound is not metabolized by the organism.

Mobility in Soil: Eugenol is expected to have moderate mobility in soil.

Other Adverse Effects: None known.

Results of PBT/vPvB Assessment: Not required.

Eugenol, U.S.P.

# **13. DISPOSAL CONSIDERATIONS**

**Regulations:** Dispose in accordance with local and national environmental regulations.

Properties (Physical/Chemical) Affecting Disposal: None known.

Waste Treatment Recommendations: None needed for normal anticipated use.

## **14. TRANSPORT INFORMATION**

| UN Number:                     | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
|--------------------------------|--|---------------------------|------------|-----------|
| UN Proper Shipping<br>Name:    | ADR/RID: Not Regulat<br>IMDG: Not Regulated<br>IATA: Not Regulated | ed                        |            |           |
|                                | DOT: Not Regulated   |                           |            |           |
| Transport Hazard<br>Class(es): | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| Packaging Group:               | ADR/RID: None  | IMDG: None                | IATA: None | DOT: None |
| Environmental<br>Hazards:      | ADR/RID: No  | IMDG Marine pollutant: No | IATA: No   | DOT: No   |

## **15. REGULATORY INFORMATION**

## **U.S. Federal Regulations**

**Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):** This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the ingredients in this product are listed on the EPA TSCA Inventory.

Clean Water Act (CWA): Not Listed

Clean Air Act (CAA): Not Listed

#### Superfund Amendments and Reauthorization Act (SARA) Title III Information:

## SARA Section 311/312 (40 CFR 370) Hazard Categories:

| Immediate Hazard: | Yes | Pressure Hazard:   | No |
|-------------------|-----|--------------------|----|
| Delayed Hazard:   | Yes | Reactivity Hazard: | No |
| Fire Hazard:      | No  |                    |    |

# This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None       |          |      |

## State Regulations

**California:** This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

| Components | C.A.S. # | WT % |
|------------|----------|------|
| None       |          |      |

## **International Regulations**

**Canadian Workplace Hazardous Materials Information System (WHMIS):** Class D, Division 2B (Toxic material causing other chronic effects).

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

# **16. OTHER INFORMATION**

Full Text of Classification Abbreviations used in Sections 2 and 3:

- R22 Harmful if swallowed.
- R38 Irritating to skin.
- R43 May cause sensitization by skin contact.
- S24 Avoid contact with skin.
- S37 Wear suitable gloves.
- S28 After contact with skin, wash immediately with plenty of water.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.