

Safety Data Sheet

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

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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	U/P Root Canal Liquid
Chemical Name/Classification:	Eugenol
Product Identifier (Part/Item Number):	11435 (1/8 oz), 11437 (1/2 oz), 11438 (2 oz), 11612 (30 Capsules), 11613 (100 Capsules), 11615
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:	1-201-871-1232 or 800-637-8582 (Product Information)-
Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
Email address:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

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

Health	Environmental	Physical
Skin Irritation Category 2 Acute Toxicity Category 4 (H302) 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.

Label Elements:**Signal Word: WARNING!**

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



Contains Eugenol

3. COMPOSITION AND INFORMATION ON INGREDIENTS

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





4. FIRST-AID MEASURES

Routes of 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 symptoms of exposure	May cause mild eye irritation. May cause skin irritation. May cause sensitization by skin contact. 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 (Treatment, Testing, and Monitoring): Treatment of overexposure should be directed at the control of symptoms and clinical 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.

Recommended Protective Equipment for Fire Fighters:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			



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
			

7. HANDLING AND STORAGE

Precautions for Safe Handling: 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
	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

Recommended Personal Protective Equipment:

EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

Environmental Exposure Controls: None required for normal 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colorless to pale yellow liquid	Explosive limits:	Not applicable
Odor:	Pungent, spicy	Vapor pressure (mmHg @ 20°C) :	0.009
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Specific Gravity: (H₂O = 1)	1.066 @ 20°C
Melting/freezing point:	15.4°F (-9.2°C)	Solubility:	Insoluble
Initial boiling point and range:	491°F (255°C)	Partition coefficient: n-octanol/water:	2.27 log Kow
Flash point:	485.6°F (252°C)	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Not flammable	Viscosity:	Not available
Explosive Properties:	None	Oxidizing Properties:	None

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.

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.

Ingestion: Swallowing may cause gastrointestinal irritation, nausea, vomiting, diarrhea, weakness, lethargy and ataxia.

Inhalation: Inhalation exposure will not occur in normal use.

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

Carcinogenicity: 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.

Mutagenicity: 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):

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

Repeated Exposure: 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.

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 name:	ADR/RID: Not Regulated IMDG: Not Regulated IATA: Not Regulated DOT: Not Regulated			
Transport hazard class(es):	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Packaging group:	ADR/RID: None	IMDG: None	IATA: None	DOT: None
Environmental hazards:	ADR/RID: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user:				

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 Section 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.