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: 10404MS
Date Revised: 20 June 2016
Revision Number:4

1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**Dry Socket Paste**
Chemical Name/Classification:	Mixture of organic compounds
Product Identifier (Part/Item Number):	10404 (1oz)
U.N. Number:	None
U.N. Dangerous Goods Classification:	None
Recommended Use:	Topical anesthetic
Restrictions on Use:	Use only as directed
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:	customer.service@sultanhc.com

2. HAZARD(s) IDENTIFICATION

EU Classification (1999/45/EC as amended): Irritant (Xi) R43

EU Labeling:

 Irritant	R43 May cause sensitization by skin contact. S24 Avoid contact with skin. S36/37 Wear suitable protective clothing and gloves.

US Hazard Classification: Hazardous

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %
Guaiacol	90-05-1 / 201-964-7	2-methoxyphenol	Xn, Xi, R22, R36/38 Acute Tox. 4 (H302), Eye Irrit. 2 (H319), Skin Irrit. 2 (H315)	1-5
Eugenol	97-53-0 / 202-589-1	2-methoxy-4-prop-2-enylphenol	Xn, Xi R22, R38, R43	1-5
Chlorobutanol, anhydrous	57-15-8 / 200-317-6	1,1,1-Trichloro-2-methyl-2-propanol	Xn R22, R36/38	1-2

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

4. FIRST-AID MEASURES

Routes of Exposure	First Aid Instructions
Eye	Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. Remove contaminated clothing and launder before reuse. Get medical attention if symptoms develop and persist.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If swallowed, rinse mouth with water. Never give anything by mouth to an unconscious person. Get medical attention.
Most Important Symptoms of Exposure	May cause eye and skin irritation. May cause allergic skin reaction. May be harmful if swallowed.
Other	Contact with skin or mucous membranes may cause numbness.
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 media appropriate for surrounding fire.
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Specific Hazards Arising from the Chemical:	None known.
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 spills, wear gloves and eye protection.
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: Wipe up with a paper towel and place into an appropriate container for disposal.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**SKIN**	**RESPIRATORY**	**THERMAL**
			

7. HANDLING AND STORAGE

Precautions for Safe Handing: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Use in accordance with package instructions.
Conditions for Safe Storage: Store in a cool, dry, well ventilated area away. Keep containers tightly closed. Protect from physical damage.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Chlorobutanol, anhydrous	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Guaiacol	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
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: No special controls required.

Individual Protection Measures (PPE)

Specific Eye/Face Protection: Safety glasses should be worn if contact is likely.

Specific Skin Protection: Wear rubber gloves to avoid contact. Recommended glove: rubber gloves. 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.			
General Hygiene Considerations and Work Practices: Wash thoroughly after handling. Remove and launder contaminated clothing before reuse.			
Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Dark brown liquid	**Explosive Limits:**	Not applicable
Odor:	Aromatic	**Vapor Pressure:**	Negligible
Odor Threshold:	Not available	**Vapor Density:**	Not available
pH: (1:1 water)	4.5 in water	**Specific Gravity: (H_2O = 1)**	0.964 @ 25°C
Melting/Freezing Point:	Not available	**Solubility:**	Not miscible
Initial Boiling Point and Range:	400°F / 204.4°C	**Partition Coefficient: n-octanol/water:**	Not available
Flash Point: PMCC	280°F / 137.8°C	**Auto-Ignition Temperature:**	Not available
Evaporation Rate:	Not available	**Decomposition Temperature:**	Not available
Flammability:	Not flammable	**Viscosity:**	800 centipoises
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: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Direct contact may cause eye irritation with blurred vision and pain. May cause anesthetic effects.

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 and central nervous system effects such as confusion, ataxia and mild hypertension. May be harmful if swallowed.

Inhalation: No effects are expected because the product is an ointment.

Chronic Health Effects: Prolonged exposure to chlorobutanol may cause kidney or liver damage.

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

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: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Guaiacol: LD50 oral rat 520 mg/kg, LD50 skin rabbit 4,600 mg/kg

Eugenol: Oral rat LD50 1930 mg/kg

Chlorobutanol: Oral rat LD50 510 mg/kg; Skin rabbit LD50 2000 mg/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 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 were observed.

12. ECOLOGICAL INFORMATION

Toxicity:

Guaiacol: 48 hr EC50 daphnia magna 25.9 mg/L

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

Persistence and Degradability: Guaiacol: Readily Biodegradable (90% in 28 days).

Bio-accumulative Potential: Guaiacol: The calculated BCF is estimated to be 3 which suggests the potential for bioconcentration in aquatic organisms is low. Eugenol: The potential for bioaccumulation is aquatic organisms is low, provided the compound is not metabolized by the organism.

Mobility in Soil: Guaiacol is expected to have very high 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: None				

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.

OSHA Hazard Classification: Irritant, Target organ effects, Sensitizer

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 Environmental Protection Act: All the components of this product are listed on the Canadian DSL.

Canadian Workplace Hazardous Materials Information System (WHMIS): Class D, Division 2B

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:

Xn	Harmful
Xi	Irritant
R22	Harmful if swallowed.
R36/38	Irritating to eyes and skin.
R38	Irritating to skin.
R43	May cause sensitization by skin contact.
Acute Tox 4	Acute Toxicity Category 4
Eye Irrit. 2	Eye Irritation Category 2
Skin Irrit. 2	Skin Irritation Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

Date of SDS Preparation/Revision: 6 December 2011

Revision Summary: Revision 3 – Updated address and contact information and updated hazard symbol to GHS image.

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