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):	**Copal Cavity Varnish**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	10314 (2oz)
U.N. Number:	UN1219
U.N. Dangerous Goods Classification:	3, PG II
Recommended Use:	Dental Varnish
Restrictions on Use:	For professional use only
Manufacturer/Supplier Name:	**Sultan Healthcare**
Manufacturer/Supplier Address:	411 Hackensack Avenue, 9th Floor Hackensack, NJ
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

EU Classification (1999/45/EC as amended): Highly Flammable (F), Irritant (Xi)

EU Labeling:

Highly Flammable

Irritant

R11 Highly flammable
R36 Irritating to eyes.
R67 Vapours may cause drowsiness and dizziness.
S16 Keep away from sources of ignition - No smoking.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S51 Use only in well-ventilated areas.

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 %
Isopropyl Alcohol	67-63-0 / 200-661-7	propan-2-ol	F, Xi R11, R36, R67 Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	80-90
Gum Copal	9000-14-0 / 232-527-9	Not available	Not classified as dangerous	10-20

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	Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Seek medical attention if irritation persists.
Skin	Wash skin thoroughly with soap and water. Remove contaminated clothing. If irritation develops, get medical attention.
Inhalation	Remove the victim to fresh air. If breathing has stopped administer artificial respiration. If breathing is difficult, have medical personnel administer oxygen. Get immediate medical attention.
Ingestion	Do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.
Most important symptoms of exposure	May cause eye irritation. Prolonged skin contact may cause irritation. Inhalation may cause headache, dizziness, drowsiness, nausea, narcosis, and unconsciousness.
Other	None known.
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, carbon dioxide, alcohol foam or dry chemical. Water spray may be used to cool exposed containers.
Fire Fighting Procedures:	Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from fire fighting to enter drains or water courses.
Specific Hazards Arising from the Chemical:	Combustion may produce oxides of carbon.
Precautions for Fire Fighters:	This product is flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Wear appropriate protective clothing, gloves and eye protection.

Environmental Precautions: Prevent spill from entering sewers and water courses. Do not flush to sewer. Report releases as required by local and national authorities.

Methods and Materials for Containment and Clean-up: Eliminate all sources of ignition and ventilate the area. Collect using an inert non-combustible absorbent material and place in appropriate container.

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. Avoid breathing vapors. Use only with adequate ventilation. Wash exposed thoroughly with soap and water after handling and before eating, drinking, smoking or using restroom.

Empty containers retain product residue and may be hazardous. Follow all precautions in SDS when handling empty containers.

Conditions for Safe Storage: Store in a cool, dry, well ventilated area away from ignition sources. Protect from physical damage.

Flammable liquid! Keep container away from excessive heat, sparks and open flames. Keep containers closed when not in use.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Gum Copal	United States	None Established.
	Germany	None Established
	United Kingdom	None Established
	France	None Established
	Spain	None Established
	Italy	None Established
	European Union	None Established
Isopropyl Alcohol	United States	400 ppm TWA OSHA PEL 200 ppm TWA ACGIH TLV, 400 ppm STEL
	Germany	200 ppm TWA DFG MAK
	United Kingdom	400 ppm TWA UK OEL, 500 ppm STEL
	France	400 ppm STEL INRS VLCT (France)
	Spain	400 ppm TWA VLA-ED, 500 ppm STEL VAL-EC (Spain)
	Italy	None Established
	European Union	None Established

Biological Exposure Limits: None Established

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits.

Individual Protection Measures (PPE)

Specific Eye/face Protection: Splash proof goggles should be worn 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 with adequate ventilation. If exposure limits are exceeded, an approved organic vapor respirator or self-contained breathing apparatus should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practices.

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: Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. 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:	Clear yellowish liquid	**Explosive limits:**	LEL: 2.0% UEL: 12.7% (isopropanol)
Odor:	Alcohol	**Vapor pressure:**	45.4 mmHg @ 25°C (isopropanol)
Odor threshold:	0.44 ppm	**Vapor density:**	2.1 (isopropanol)
pH:	Not available	**Specific Gravity: (H_2O = 1)**	Not available
Melting/freezing point:	-127.3°F (-88.5°C) (isopropanol)	**Solubility:**	Not soluble
Initial boiling point and range:	181°F (82.5°C) (isopropanol)	**Partition coefficient: n-octanol/water:**	Not available
Flash point (CC):	53°F (12°C) (isopropanol)	**Auto-ignition temperature:**	750°F (399°C) (isopropanol)
Evaporation rate:	1.7 (butyl acetate =1) (isopropanol)	**Decomposition temperature:**	Not available
Flammability:	Flammable	**Viscosity:**	Not available
Explosive Properties:	Explosive vapor concentrations may collect in confined areas.	**Oxidizing Properties:**	None

10. STABILITY AND REACTIVITY

Reactivity: This product is not reactive under normal conditions of use.
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions: Reaction with oxidizers may generate heat and cause fire.
Conditions to Avoid: Keep away from heat, sparks, flames and all other sources of ignition.
Incompatible materials: Avoid strong oxidizing agents, strong acids and bases.
Hazardous Decomposition Products: Thermal decomposition may produce carbon monoxide and carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Vapors may cause eye irritation with redness, tearing and swelling.

Skin: Prolonged contact may cause irritation and drying of the skin.

Ingestion: May cause gastrointestinal irritation, nausea, vomiting and diarrhea and other symptoms listed under inhalation.

Inhalation: Inhalation of vapors may cause respiratory tract irritation and central nervous system effects including headache, dizziness, drowsiness, narcosis and unconsciousness.

Chronic Health Effects: Prolonged and/or repeated overexposure to isopropanol may cause damage to the kidneys, liver, and central nervous system based on animal data.

Carcinogenicity: Isopropyl alcohol: There is inadequate evidence of carcinogenicity in humans and animals.

Mutagenicity: Isopropyl Alcohol: In an in-vivo study, isopropanol did not induce micronuclei in bone marrow of mice. Studies conducted in mammalian cells in-vitro, did not induce sister chromatid exchanges or gene mutations.

Medical Conditions Aggravated by Exposure: Persons with existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:

Isopropyl Alcohol: Oral rat LD50 5,045 mg/kg, Skin rabbit LD50 12,800 mg/kg

Gum Copal: No data available

Reproductive Toxicity Data: Isopropyl Alcohol: A 73 week chronic study found male reproductive effects at 2,500 and 5,000 ppm.

Specific Target Organ Toxicity (STOT):

Single Exposure: None known.

Repeated Exposure: Isopropyl Alcohol: A 13 week inhalation study with rats found effects of narcosis at 5,000 ppm. These effects were reversible at the cessation of exposure. A 73 week chronic study found male reproductive effects at 2,500 and 5,000 ppm and liver effects at 2,500 ppm.

12. ECOLOGICAL INFORMATION

Toxicity:

Isopropanol: 96 hr LC50 fish (fathead minnow) 8300 mg/L, 48 hr LC50 daphnia 7550 mg/L

Persistence and Degradability:
Isopropanol: Readily biodegradable.

Bio-accumulative Potential:

Isopropanol has a BCF of 3 which suggests the potential for bioaccumulation in aquatic animals is low.

Mobility in Soil:

Isopropanol is expected to have very high mobility in soil.

Other Adverse Effects: No data available for product.

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 known.

14. TRANSPORT INFORMATION

UN Number:	ADR/RID: UN1219	IMDG: UN1219	IATA: UN1219	DOT: UN1219
UN proper shipping name:	ADR/RID: Isopropanol, mixture IMDG: Isopropanol, mixture IATA: Isopropanol, mixture DOT: Isopropanol, mixture			
Transport hazard class(es):	ADR/RID: 3	IMDG: 3	IATA: 3	DOT: 3
Packaging group:	ADR/RID: II	IMDG: II	IATA: II	DOT: II
Environmental hazards:	ADR/RID: None	IMDG Marine pollutant: None	IATA: None	DOT: None
Special precautions for user: Flammable Liquid				

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: Flammable Liquid, Target organ effects, Irritant

Clean Water Act (CWA): None listed

Clean Air Act (CAA): None 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:	**Yes**		

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 B - Division 2 (Flammable Liquid), Class D - Division 2 - Subdivision B - (Toxic material causing other toxic effects: Carcinogen)

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:

F Highly Flammable
Xi Irritant
R11 Highly flammable
R36 Irritating to eyes.
R67 Vapors may cause drowsiness and dizziness

Flamm. Liq. 2 Flammable Liquid Category 2
Eye Irrit. 2 Eye Irritant Category 2
STOT SE 3 Specific Target Organ Toxicity (Single Exposure) Category 3
H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Date of SDS Preparation/Revision: 6 December 2011

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