

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
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 Revision Number: 6

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	Copal Cavity Varnish
Part/Item Number:	10314 (2oz)

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Dental Varnish
Restrictions on Use:	For professional use only

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Sultan Healthcare
Manufacturer/Supplier Address:	1301 Smile Way York, PA, USA
Manufacturer/Supplier Telephone Number:	1-201-871-1232 or 800-637-8582 (Product Information)-
Email address:	customer.service@sultanhc.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	800-535-5053 (INFOTRAC) 1-352-323-3500 (Outside the United States – Call Collect)
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2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS SDS Classification:

Health	Environmental	Physical
Eye Irritation Category 2 Specific Target Organ Toxicity – Single Exposure Category 3 H336	Not Hazardous	Flammable Liquid Category 2

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

EU Risk (R) Phrases: R11, R36/37, R67

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

2.2 Labeling Elements:



Signal Word: Danger!

Hazard Statements	Precautionary Statements
<p>H225 Highly flammable liquid and vapor. H319 Causes serious eye irritation. H335 May cause respiratory irritation H336 May cause drowsiness or dizziness.</p>	<p>P210 Keep away from heat, sparks, open flames, and hot surfaces. No smoking. P233 Keep container tightly closed. P240 Ground and bond container and receiving equipment P241 Use explosion-proof electrical, ventilating and lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P261 Avoid breathing mist, vapors or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves, eye protection and face protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P370 + P378 In case of fire: Use water spray, carbon dioxide, alcohol foam or dry chemical to extinguish. P403 + P235 Store in a well-ventilated place. Keep cool. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents and container in accordance with local and national regulations.</p>

2.3 Other Hazards: None

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. # EC#	IUPAC Name	CLP/GHS / EU Classification (1272/2008) (1999/45/EC)	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	Xi R36/37 Eye Irrit. 2; H319 STOT SE 3; H336	10-20

The exact concentration is being withheld as a trade secret.

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

4. FIRST-AID MEASURES

4.1 Description of 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.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause eye irritation. Prolonged skin contact may cause irritation. Inhalation may cause headache, dizziness, drowsiness, nausea, narcosis, and unconsciousness.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

None required under normal use.

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

5.1 Extinguishing Media





Use water spray, carbon dioxide, alcohol foam or dry chemical. Water spray may be used to cool exposed containers.

5.2 Special Hazards Arising from the Substance or Mixture:



Combustion may produce oxides of carbon.

5.3 Advice for Fire-Fighters:

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.
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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

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Wear appropriate protective clothing; gloves and eye protection.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

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

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

6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:
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.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

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.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

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

8.2 Exposure Controls:

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. 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
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic 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	Relative density:	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:	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

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: This product is not reactive under normal conditions of use.

10.2 Chemical Stability: Stable under normal conditions of use.

10.3 Possibility of Hazardous Reactions: Reaction with oxidizers may generate heat and cause fire.

10.4 Conditions to Avoid: Keep away from heat, sparks, flames and all other sources of ignition.

10.5 Incompatible materials: Avoid strong oxidizing agents, strong acids and bases.

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

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

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

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

12.2 Persistence and Degradability. Isopropanol: Readily biodegradable.

12.3 Bio-accumulative Potential: Isopropanol has a BCF of 3 which suggests the potential for bioaccumulation in aquatic animals is low.

12.4 Mobility in Soil: Isopropanol is expected to have very high mobility in soil.

12.5 Other Adverse Effects: No data available for product.

12.6 Results of PBT/vPvB Assessment: Not required

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

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

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	UN1219	Isopropanol mixture	3	PG II	None
ADR/RID	UN1219	Isopropanol mixture	3	PG II	None
IMDG	UN1219	Isopropanol mixture	3	PG II	Marine Pollutant-None
IATA/ICAO	UN1219	Isopropanol mixture	3	PG II	None

14.6 Special precautions for user: Flammable Liquid

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable – product is transported only in packaged form.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

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

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.

Supersedes: 13 February 2012

Revision Summary: Comprehensive review, new format.

Date of SDS Preparation/Revision: 02 September, 2014

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