

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): Durashield® CV – 5% Sodium Fluoride Clear Varnish

Chemical Name/Classification: Mixture

Product Identifier (Part/Item Number): 31103, 31104, 31105, 31106

U.N. Number: UN1219

U.N. Dangerous Goods Classification: 3

Recommended Use: Desensitizing agent

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

Hazard/Danger Classification (Regulation EC) No. 1272/2008 [CLP] / Hazcom 2012:

Health	Environmental	Physical
Acute Toxicity Category 4 Skin Sensitizer Category 1 Eye Irritant Category 2 Specific Target Organ Toxicity –Single Exposure Category 3	Non-Hazardous	Flammable Liquid Category 2

EU Classification(1999/45/EC as amended): Harmful (Xn), Irritant (Xi)

EU Risk (R) Phrases: R22, R36, R43, R67

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

Labeling Elements: Contains 2-Propanol and Sodium Fluoride



Signal Word: Danger

Hazard Statements	Precautionary Statements
<p>H225 Highly flammable liquid and vapor H302 Harmful if swallowed H317 May cause an allergic skin reaction. H319 Causes serious eye 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. P261 Avoid breathing vapors. P264 Wash exposed skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves, protective clothing, eye protection, and face protection. 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 P303 + P361 + P353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P363 Wash contaminated clothing before reuse. P304 + P340 IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor/physician if you feel unwell. P301 + P312 IF SWALLOWED: Call a POISON CENTER, doctor if you feel unwell P330 Rinse mouth. P370 + P378 In case of fire: Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray to extinguish. P403 + P235 Store in a well-ventilated place. Keep cool. P405 Store locked up. . P501 Dispose of contents and container in accordance with local and national regulations.</p>

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Components	C.A.S. # EC#	IUPAC Name	Substance Classification 67/548/EEC (EC) No 1272/2008	WT %
Sodium Fluoride	7681-49-4 / 231-667-8	Sodium Fluoride	T R25, R36/38, R32 Acute Tox. 3; H301 Eye Irrit. 2; H319 Skin Irrit. 2; H315	5
2-Propanol	67-63-0 / 200-661-7	propan-2-ol	F R11, R36, R67 Eye Irrit. 2 H319 STOT SE 3 H336 Flam. Liq. 2, H225	20-25
Proprietary Synthetic Resin	Proprietary	Proprietary	Xi R43 Skin Sens. 1; H317	< 45





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 15 minutes, holding the eyelids apart. Get immediate medical attention.
Skin	Remove contaminated clothing. Wash skin with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Rinse out mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious or drowsy person. Get immediate medical attention.
Most important symptoms of exposure	May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed. Vapors may cause drowsiness and dizziness.
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 carbon dioxide, alcohol-resistant foam, dry chemical and water spray.
Fire Fighting Procedures:	Cool fire exposed containers with water spray.
Specific Hazards Arising from the Chemical:	Highly flammable liquid and vapor. Closed containers exposed to heat from fire may build pressure and explode.



Precautions for Fire Fighters:		Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.	
Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, PPE and Emergency Procedures: Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Environmental Precautions: Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities.

Methods and Materials for Containment and Clean-up: Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water.

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 the eyes and skin. Avoid breathing vapors. Wear protective clothing and equipment as described in Section 8. Keep product away from heat, sparks, flames and other sources of ignition. Use with adequate ventilation. Wash thoroughly after handling. Use in accordance with package instructions.

Empty containers retain product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

Conditions for Safe Storage: Store in a cool, well ventilated area away from oxidizing agents and direct sunlight. Avoid excessive heat and ignition sources.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits:

Sodium Fluoride (as Fluoride)	United States	2.5 mg/m ³ ACGIH TLV TWA 2.5 mg/m ³ US OSHA PEL TWA
	Germany	1 mg/m ³ (Inhalable) TWA, 4 mg/m ³ STEL DFG MAK
	United Kingdom	2.5 mg/m ³ TWA UK OEL
	France	2 mg/m ³ INRS VME
	Spain	2.5 mg/m ³ VLA-ED
	Italy	2.5 mg/m ³ 8 hr Italy Value Limit
	European Union	2.5 mg/m ³ TWA EU IOEL
2-Propanol	United States	400 ppm TWA OSHA PEL 200 ppm TWA, 400 ppm ACGIH TLV STEL
	Germany	200 ppm TWA, 40 ppm STEL DFG MAK
	United Kingdom	400 ppm TWA, 500 ppm STEL UK OEL
	France	400 ppm TWA INRS VLCT
	Spain	400 ppm TWA VLA-ED, 500 ppm VAL-EC
	Italy	None Established
	European Union	None Established
Proprietary Synthetic Resin	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:

Sodium Fluoride (as fluorides) – Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine (ACGIH)



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: Chemical safety goggles should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear plastic or rubber gloves to avoid contact. Recommended glove: Rubber gloves. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be

<p>based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice. Specific Thermal Hazards: Not applicable</p>			
<p>Recommended Personal Protective Equipment:</p>			
EYES/FACE	SKIN	RESPIRATORY	THERMAL
			
<p>Environmental Exposure Controls: None required for normal use.</p>			
<p>General Hygiene Considerations and Work Practices: Wash thoroughly after handling. Avoid contact with eyes, skin, and clothing. Remove and launder contaminated clothing before reuse.</p>			
<p>Protective Measures During Repair and Maintenance of Contaminated Equipment: Not applicable for product.</p>			

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Viscous liquid	Explosive limits:	LEL: 2.0 % (2-Propanol) UEL: 12.7 % (2-Propanol)
Odor:	Fruity	Vapor pressure:	Not available
Odor threshold:	Not available	Vapor density:	Not available
pH:	Not available	Relative density:	1.05 g/mL
Melting/freezing point:	Not available	Solubility:	Not available
Initial boiling point and range:	106°C (222.8°F)	Partition coefficient: n-octanol/water:	Not available
Flash point:	16.9°C (62.4°F) Method: Closed Cup	Auto-ignition temperature:	Not available
Evaporation rate:	Not available	Decomposition temperature:	Not available
Flammability:	Highly flammable under fire conditions.	Viscosity:	2200 – 4500 cp
Explosive Properties:	None	Oxidizing Properties:	None

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: Contact with acids liberates toxic gas.

Conditions to Avoid: Keep away from heat, sparks and all ignition sources.

Incompatible materials: Avoid acids and oxidizing materials.

Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, phosgene, hydrogen chloride and/or hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: May cause moderate irritation with redness, tearing and blurred vision.

Skin: Prolonged or repeated contact may cause mild skin irritation redness, rash and swelling. May cause allergic skin reaction (sensitization).

Ingestion: Ingestion may cause irritation to the mouth, throat and stomach with abdominal pain and nausea. May cause gastrointestinal irritation and central nervous system depression with symptoms similar to those described under inhalation.

Inhalation: Inhalation may cause nose and throat irritation with the possibility of central nervous system depression. Symptoms of central nervous system depression include headache, dizziness, drowsiness, nausea and unconsciousness.

Chronic Health Effects: Prolonged overexposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottled tooth enamel.

Carcinogenicity: A 2-year study in rats found a weak, equivocal fluoride-related increase in the occurrence of osteosarcomas in male rats, and no evidence of carcinogenicity in female rats or male or female mice. The weight of the evidence indicates that fluoridation of water does not increase the risk of developing cancer. IARC has determined that the carcinogenicity of fluoride to humans is not classifiable. None of the components of this product are listed as carcinogens by OSHA, IARC, ACGIH, NTP or EU Directives.

Mutagenicity: Sodium fluoride was negative in the AMES test but was positive a mouse lymphoma cells assay. Sodium fluoride did not induce DNA strand breaks in testicular cells of rats treated in-vivo and did not cause chromosomal aberrations in bone marrow or testicular cells or sister chromatid exchanges in bone marrow cells of mice treated in-vivo.

Medical Conditions Aggravated by Exposure: Employees with pre-existing skin disorders may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Fluoride: Oral Rat LD50 32 mg/kg

Proprietary Synthetic Resin: Oral Rat LD50- >5000 mg/kg

2-Propanol: Oral rat LD50- 5045 mg/kg; Inhalation rat LC50 – 16000 ppm /8hr; Skin rabbit LD50- 12800 mg/kg

Reproductive Toxicity Data: Sodium Fluoride: A 75 day reproductive study with rats with doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular

histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity. At doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found.

Specific Target Organ Toxicity (STOT):

Single Exposure: Sodium Fluoride: In a human exposure study, adults were given 250 mg. Effects included nausea, vomiting, epigastric distress, salivation and itching of the hands and feet. In an acute study, dogs were infused with an acute dose of 36 mg/kg. Death occurred in less than 65 minutes. Principal effects included a decline in blood pressure, heart rate, central nervous system activity, vomiting and defecation.

Repeated Exposure: Sodium Fluoride: Brain, liver, kidney and muscles demonstrate significant changes in essential trace element levels in adult female mice given 30, 60 and 120 ppm sodium fluoride in drinking water. Rats exposed to sodium fluoride in drinking water for 2 months developed thyroid effects; LOAEL 0.5 mg/kg/day. Mice exposed to sodium fluoride in drinking water for 4 weeks showed increased bone formation. LOAEL 0.8 mg/kg/day.

12. ECOLOGICAL INFORMATION

Toxicity:

Proprietary Synthetic Resin: 48hr EC50 Daphnia magna - >1.2 mg/l; 72 hr EC50 Desmodesmus subspicatus (algae)->0.68 mg/L (growth rate)

2-Propanol: 96 hr LC50 Fathead minnow – 9640 mg/L; 24 hr EC50 Water flea- 9714 mg/L

Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) - 83.7 mg/L, 48 hr EC50 Daphnia magna - 98 mg/L

Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Proprietary Synthetic Resin: 22% after 28 days - Not readily biodegradable. 2-Propanol: 95% after 21 days- Readily biodegradable.

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

Other Adverse Effects: No data available

Results of PBT/vPvB Assessment: No data available

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: UN1219 IMDG: UN1219 IATA: UN1219 DOT: UN1219

UN proper shipping name:	ADR/RID: Isopropanol Solution IMDG: Isopropanol Solution IATA: Isopropanol Solution DOT: Isopropanol Solution			
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: No	IMDG Marine pollutant: No	IATA: No	DOT: No
Special precautions for user: Not applicable				

15. REGULATORY INFORMATION

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has an RQ of 20,000 lbs based on the RQ of sodium fluoride of 1,000 lbs present at 5%. Many other states have more stringent regulations. Report all spills in accordance with local, state, and federal regulations.

Toxic Substances Control Act (TSCA): This product is a drug and not subject to chemical notification requirements.

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:	No	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 chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Components	C.A.S. #	WT %
None		

International Regulations

EU REACH: This product is a medicinal product and not subject to registration requirements.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

F Highly Flammable

T Toxic

Xi Irritant

Xn Harmful

F11 Highly Flammable

R22 Harmful if swallowed.

R25 Toxic if swallowed.

R32 Contact with acids liberates very toxic gas.

R36 Irritating to eyes.

R36/38 Irritating to eyes and skin.

R43 May cause sensitization by skin contact.

R67 Vapours may cause drowsiness.

Acute Tox. 3 Acute Toxicity Category 3

Acute Tox. 4 Acute Toxicity Category 4

Eye Irrit. 2 Eye Irritant Category 2

Flamm. Liq. 2 Flammable Liquid Category 2

Skin Irrit. 2 Skin Irritation Category 2

Skin Sens. 1 Skin Sensitizer Category 2

STOT SE 3 Specific Target Organ Toxicity Single Exposure Category 3

H225 Highly flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness

Date of SDS Preparation/Revision: 11 December 2012

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