

Safety Data Sheet

Data Sheet conforms to Regulation (EC) 1907/2006,
 Regulation (EC) 1272/2008 and Regulation (EC) 2020/878,
 US 29CFR1910.1200, Canada Hazardous Products
 Regulation

Date Issued: 19 November 2012
 Document Number: 0031103MS
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 Revision Number: 9

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

1.1 Product Identifier:

Trade Name (as labeled):	Durashield® CV – 5% Sodium Fluoride Clear Varnish
Part/Item Number:	31103, 31104, 31105, 31106, 31170, 31171, 31172, 31173, 31176, 31177, 31180, 31181

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

Recommended Use:	Desensitizing agent
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, 17404
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:

Transportation Emergency Contact Number:	800-424-9300 (Chemtrec)
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2. HAZARD(S) IDENTIFICATION

2.1 Classification of the Substance or Mixture

GHS Classification:		
Health	Environmental	Physical
Eye Irritant Category 2 (H319) Skin Sensitizer Category 1 (H317) Specific Target Organ Toxicity –Single Exposure Category 3 (H336)	Aquatic Chronic Toxicity Category 2 (H411)	Flammable Liquid Category 2 (H225)

2.2 Labeling Elements:



Signal Word: Danger

Contains: 2-Propanol and Sodium Fluoride

Hazard Statements	Precautionary Phrases
<p>H225 Highly flammable liquid and vapor. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. H411 Toxic to aquatic life with long lasting effects. EUH032 Contact with acids liberates very toxic gas.</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 vapors. P264 Wash exposed skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing must not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves, and eye protection. P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P333 + P313 If skin irritation or rash occurs: Get medical 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. 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. P370 + P378 In case of fire: Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray to extinguish. P391 Collect spillage. 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>

2.3 Other Hazards: None known.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

3.2 Mixture

Hazardous Components	C.A.S. #	EINECS # / REACH Registration #	Classification	WT %
Urethane Dimethacrylate Resin	72869-86-4	276-957-5 /	Skin Sens.1B (H317) Aqua. Chron. 2 (H411)	< 45
2-Propanol	67-63-0	200-661-7 /	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319) At 50% STOT SE 3 (H336)	20-25
Sodium Fluoride	7681-49-4	231-667-8 /	Acute Tox. 3 (H301) LD50-148.5 mg/kg Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) EUH032	5

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS Classifications.

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 15 minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin with soap and water. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	Rinse out mouth with water. Do not induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious or drowsy person. Get medical attention.

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

May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed. If swallowed, may cause gastrointestinal irritation. Vapors may cause drowsiness and dizziness.

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

None required under normal conditions of use.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:

Use carbon dioxide, alcohol-resistant foam, dry chemical and water spray.

5.2 Special Hazards Arising from the Substance or Mixture:

Highly flammable liquid and vapor. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers exposed to heat from fire may build pressure and explode.

5.3 Advice for Fire-Fighters:

Fire Fighting Procedures/ Precautions for Fire Fighters:

Cool fire exposed containers and structures with water spray. Firefighters should wear full emergency equipment and approved positive pressure self-containing breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Ventilate the area. Avoid contact with skin, eyes or clothing. Avoid breathing vapors, mist, or spray. Wear appropriate protective clothing as described in Section 8.

6.2 Environmental Precautions:

Prevent spill from entering sewers and waterways. Report releases as required by local and national authorities.

6.3 Methods and Material for Containment and Cleaning Up:

Clean up with absorbent material and remove residue with alcohol damp wipe. Place in appropriate containers for disposal. Rinse spill area with water.

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 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.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Urethane Dimethacrylate Resin	None Established
2-Propanol	200 ppm TWA, 400 ppm STEL ACGIH TLV 400 ppm TWA OSHA PEL 400 ppm TWA, 500 ppm STEL UK OEL 400 ppm STEL France OEL 200 ppm TWA, 400 ppm STEL DFG MAK 200 ppm TWA, 400 ppm STEL Belgium OEL
Sodium Fluoride (As Fluoride F)	2.5 mg/m ³ TWA ACGIH TLV 2.5 mg/m ³ TWA OSHA PEL 2.5 mg/m ³ TWA France OEL 1 mg/m ³ TWA (inhalable), 4 mg/m ³ STEL (inhalable) DFG MAK 2.5 mg/m ³ TWA Belgium OEL
Biological Exposure Limits: Sodium Fluoride (as fluorides) – Prior to shift 3 mg/g creatinine; End of shift 10 mg/g creatinine (ACGIH) 2-Propanol – End of shift at end of work week. Acetone in urine 40 mg/L. (ACGIH)	
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: Chemical safety glasses or goggles recommended. 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 based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice. Specific Thermal Hazards: Not applicable	

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:			
Appearance:	Viscous Liquid	Explosive Limits:	LEL: 2.0 % (2-Propanol) UEL: 12.7 % (2-Propanol)
Color:	Colorless	Physical State:	Liquid
Odor:	Fruity	Vapor pressure (mmHg):	Not Available
Odor Threshold:	Not Available	Relative Vapor Pressure @20°C: (Air = 1)	Not Available
pH:	Not applicable	Relative Density:	1.05
Melting/Freezing Point:	Not Available	Solubility(ies):	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 liquid.	Kinematic Viscosity:	Not determined

9.2.1 Properties, Safety Characteristics and Test Results for Physical Hazards:

Dynamic Viscosity: 2200 – 4500 cp

9.2.2 Other Safety Characteristics: None determined

10. STABILITY AND REACTIVITY

10.1 Reactivity: Not reactive.
10.2 Chemical Stability: Stable.
10.3 Possibility of Hazardous Reactions: Contact with acids liberates toxic gas.
10.4 Conditions to Avoid: Keep away from heat, sparks, flames and all ignition sources.
10.5 Incompatible Materials: Avoid acids and oxidizing materials.
10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon monoxide, carbon dioxide, phosgene, hydrogen chloride and/or hydrogen fluoride.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

<u>Potential Health Effects:</u> <u>Eyes:</u> May cause moderate irritation with redness, tearing and blurred vision. <u>Skin:</u> Prolonged or repeated contact may cause mild skin irritation redness, rash and swelling. May cause allergic skin reaction (sensitization). <u>Ingestion:</u> 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. <u>Inhalation:</u> 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.
<u>Chronic Health Effects:</u> None expected under normal use. 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.
<u>Eye Irritation / Damage:</u> 2-Propanol: Causes serious eye irritation in rabbit eyes. Sodium fluoride: Not irritating to rabbit eyes or skin.
<u>Skin Irritation / Corrosivity:</u> Based on available data, the classification criteria are not met.
<u>Sensitization:</u> Urethane Dimethacrylate Resin is classified as a skin sensitizer.
<u>Carcinogenicity:</u> Based on available data, the classification criteria are not met. 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 CLP.
<u>Mutagenicity:</u> Based on available data, the classification criteria are not met. 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.
<u>Aspiration Hazard:</u> Based on available data, the classification criteria are not met.

Acute Toxicity Data:

ATE Product: Oral LD50: 2970 mg/kg

Urethane dimethacrylate Resin: Oral Rat LD50: >5000 mg/kg; Skin rat LD50: >2000 mg/kg

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

Sodium Fluoride: Oral Rat LD50: 148.5 mg/kg

Reproductive Toxicity Data: Based on available data, the classification criteria are not met. 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 Single Exposure (STOT-SE):

2-Propanol: Vapors 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.

Specific Target Organ Toxicity Repeated Exposure (STOT-RE): Based on available data, the classification criteria are not met. 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.

11.2 Information on Other Hazards**11.2.1 Endocrine Disrupting Properties:** None known**12. ECOLOGICAL INFORMATION****12.1 Toxicity:**

Urethane dimethacrylate Resin: 96 hr LC50 Zebra fish – 10.1 mg/L; 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

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

12.3 Bio-accumulative Potential: No data available**12.4 Mobility in Soil:** No data available**12.5 Results of PBT and vPvB Assessment:** Not required**12.6 Endocrine disrupting Properties:** None known.**12.7 Other Adverse Effects:** None known**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: Treat in accordance with national and local regulations.

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 Solution	3	PG II	No
ADR/RID	UN1219	Isopropanol Solution	3	PG II	No
IMDG	UN1219	Isopropanol Solution	3	PG II	No
IATA/ICAO	UN1219	Isopropanol Solution	3	PG II	No

14.6 Special precautions for user: Not applicable

14.7 Transport in Bulk According to IMO Instruments: 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 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): 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: See OSHA Hazard Classification in Section 2.

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372): None.

State Regulations

California: This product does not contain substances known to the state of California to cause cancer and/or reproductive toxicity.

International Regulations

EU REACH: The substances in this product comply with the EU REACH regulation as applicable.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health –2 Flammability – 3 Reactivity – 0

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

Acute Tox. 3 - Acute Toxicity Category 3
Aqua. Chron. 2 - Hazardous to the Aquatic Environment – Long-Term Hazard Category 2
Eye Irrit. 2 - Eye Irritant Category 2
Flamm. Liq. 2 - Flammable Liquid Category 2
Skin Irrit. 2 - Skin Irritation Category 2
Skin Sens. 1B - Skin Sensitizer Category 1B
STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly flammable liquid and vapour.
H301 Toxic if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects
EUH032 Contact with acids liberates very toxic gas.

Supersedes: 09 September 2019

Date Updated: 21 September 2021

Revision Summary: Three year update. Remove EU classifications. Revise format. Changes to all Sections..

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, ECHA REACH Registration Website, Country websites for occupational exposure limits.