PREVENTECH®

Safety Data Sheet

Document Number: RM142
Date Revised: 07 May 2014
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1. PRODUCT IDENTIFICATION

Trade Name (as labeled):	**VELLA® 5% Sodium Fluoride Varnish with Xylitol®**
Chemical Name/Classification:	Mixture
Product Identifier (Part/Item Number):	770013, 770033, 770023, 770043, 770073, 770083, 770103, 770113
U.N. Number:	1986
U.N. Dangerous Goods Classification:	3 (6.1) **Packaging Group:** II
Recommended Use:	Enamel / Dentin Desensitizing agent
Restrictions on Use:	For professional dental in-office use only
Manufacturer/Supplier Name:	Preventive Technologies, Inc. (www.preventech.com)
Manufacturer/Supplier Address:	4330C Matthews- Indian Trail Road Indian Trail NC 28079
Manufacturer/Supplier Telephone Number:	1-704-849-2416 or 1-800-474-8681 (Product Information)
Email address:	customerservice@preventech.com

2. HAZARD(s) IDENTIFICATION

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

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 Toxicity 3, H301 Eye Irritation 2, H319 Skin Irritation 2, H315	5%
Ethanol	64-17-5 / 200-578-6	ethanol	F R11 Flammable Liquid 3, H225	25-30%
Synthetic Resin	Proprietary	Proprietary	Xi R43 Skin Sensitization 1, H317	<60%

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	Wash skin with soap and water. Get medical attention if irritation or symptoms develop.
Inhalation	None needed under normal use conditions. If irritation develops, remove to fresh air. Get medical attention if symptoms persist.
Ingestion	If over normal dose is swallowed, DO NOT induce vomiting. Drink large quantities of water, milk or several ounces of milk of magnesia. Contact poison control.
Most important symptoms of exposure	May cause eye and skin irritation. Vapors may cause irritation and central nervous system effects. May cause allergic skin reaction (sensitization). May be harmful if large amounts are swallowed.
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 dry chemical, alcohol- resistant foam or carbon dioxide.
Fire Fighting Procedures:	Cool fire exposed containers and structures with water.
Specific Hazards Arising from the Chemical:	Flammable liquid and vapor. Vapors are heavier than air and may travel to a remote ignition source and flashback.
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 large spills, wear protective clothing, eye protection and gloves. For small spills, wear eye protection and gloves.
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: Collect using an inert non-combustible absorbent material and place in appropriate containers 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 the eyes and skin. Avoid breathing vapors. Keep product away from heat, sparks, flames and other sources of ignition. Use with adequate ventilation. Use in accordance with package instructions.
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	.5 mg/m3 ACGIH TLV TWA 2.5 mg/m3 US OSHA PEL TWA
	Germany	2.5 mg/m3 TWA EU IOEL
	United Kingdom	2.5 mg/m3 TWA UK OEL
	France	2 mg/m3 INRS VME
	Spain	2.5 mg/m3 VLA-ED
	Italy	2.5 mg/m3 8 hr Italy Value Limit
	European Union	2.5 mg/m3 TWA EU IOEL
Ethanol	United States	1000 ppm TWA OSHA PEL 1000 ppm TWA ACGIH TLV STEL
	Germany	500 ppm TWA DFG MAK
	United Kingdom	1000 ppm TWA UK OEL
	France	1000 ppm TWA INRS VME, 5000 ppm VLCT
	Spain	1000 ppm TWA VLA-ED
	Italy	None Established
	European Union	None Established
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 and local ventilate to minimize exposure levels.

Individual Protection Measures (PPE)

Specific Eye/Face Protection: Safety glasses should be worn if contact is likely.
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 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:	Off-White Viscous Liquid	**Explosive limits:**	LEl: 3.3 (ethanol) UEL: 19 (ethanol)
Odor:	Characteristic of product flavor	**Vapor pressure:**	Not available
Odor threshold:	Not available	**Vapor density:**	Not available
pH:	Not available	**Relative density:**	1.05g/mL
Melting/freezing point:	Not available	**Solubility:**	Not available
Initial boiling point and range:	Not available	**Partition coefficient: n-octanol/water:**	Not available
Flash point:	28°C / 82°F	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not available	**Decomposition temperature:**	Not available
Flammability:	Not flammable	**Viscosity:**	<6000cps
Explosive Properties:	None	**Oxidizing Properties:**	None

10. STABILITY AND REACTIVITY

Reactivity: Not reactive.

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

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

Incompatible materials: Avoid oxidizing agents.

Hazardous Decomposition Products: Thermal decomposition may produce carbon oxides.

11. TOXICOLOGICAL INFORMATION

Potential Health Effects:

Eyes: Causes irritation with redness, tearing and swelling of conjunctiva.

Skin: Prolonged skin contact may cause irritation. May cause sensitization by skin contact.

Ingestion: Swallowing may cause nausea, vomiting, diarrhea and central nervous system depression. Large doses of fluorides can bind with serum calcium resulting in hypocalcemia with toxic effects, including cardiac effects, due to electrolyte imbalance.

Inhalation: None expected from normal use. Large vapor concentrations may cause headache, dizziness, drowsiness and other central nervous system effects.

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. Ethanol: In a skin painting study with mice, a 50% solution was placed on the skin three times a day for 829 days. No skin tumors were observed. 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. Ethanol: Negative in AMES test, in-vivo rat cytogenetic assay. Positive in a sister chromatid and exchange CHO cells, human lymphocytes cytogenetic assay, in-vivo mouse cytogenetic assay and rat dominant lethal assay.

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
Ethanol: LD50 Rat oral 7,060 mg/kg, LC50 Rat inhalation 20,000 ppm/ 10 hr
Synthetic Resin:Oral Rat LD50 ->5000mg/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. Ethanol: Ingestion of alcohol is known to have adverse effects on reproduction and development in humans.

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, salvation 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. Ethanol: No adverse effects were observed in a 90 day inhalation study with rats at an exposure of 86 mg/m3. Liver damage was observed in an 85 day study with rats at a dose of 80 ml/kg/day.

12. ECOLOGICAL INFORMATION

Toxicity:
Sodium Fluoride: 96 hr LC50 Oncorhynchus mykiss (Rainbow trout) 83.7 mg/L, 48 hr EC50 daphnia magna 98 mg/L
Ethanol: 96 hr LC50 fathead minnow 4,200 mg/L, 48 hr EC50 daphnia magna
Synthetic resin:: 48 hr EC50 daphnia magna >1.5mg/L

Persistence and Degradability: Biodegradation is not applicable to inorganic substances such as sodium fluoride. Ethanol: Readily biodegradable (84% after 20 days). Resin has been shown to degrade >25% in 28 days.

Bio-accumulative Potential: No data is available

Mobility in Soil: Ethanol has a high mobility in soil.

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:	IMDG:	IATA:	DOT:
UN proper shipping name:	ADR/RID: Ethanol IMDG: Ethanol IATA: Ethanol DOT: Ethanol			
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: No 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 chemicals(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
F11 Highly Flammable
R25 Toxic if swallowed.
R36/38 Irritating to eyes and skin.
R32 Contact with acids liberates very toxic gas.
R43 May cause sensitization by skin contact.
Flamm. Liq. 3 Flammable Liquid Category 3, ETHANOL UN# 1986
Acute Tox. 3 Acute Toxicity Category 3
Skin Irrit. 2 Skin Irritation Category 2
Eye Irrit. 2 Eye Irritant Category 2
Skin Sens. 1 Skin Sensitizer Category 2
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.

Date of SDS Preparation/Revision: 07 May 2014 Rev. C Supercedes: 02/2010 Rev. B

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