

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071472232

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

072347888 072347896

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**



071472240 071472257

## SAFETY DATA SHEET

### SECTION 1 – IDENTIFICATION

<b>Product Name:</b>	ProGuard™ 5% Sodium Fluoride Varnish
<b>Synonyms:</b>	ProGuard, Varnish
<b>Product Code(s):</b>	UFVPM and UFVPMML
<b>Recommended Use:</b>	Dental varnish. ProGuard Varnish is a dental varnish intended for use as a treatment for hypersensitive teeth; to seal the dentinal tubules for cavity preparations or on sensitive root surfaces and as a cavity liner under amalgam restorations
<b>Restrictions:</b>	Use only as directed. For use by dental professional only.
<b>Company:</b>	Crosstex 6789 W. Henrietta Road Rush, New York 14542 800-722-1529
<b>Emergency Telephone Number:</b>	INFOTRAC: 24-Hour Number: 1-800-535-5053 International: +1-352-323-3500

### SECTION 2 – HAZARD(S) IDENTIFICATION

<b>Pictograms:</b>	 Flammable Liq. 3 H226 Flammable liquid and vapor   Acute Tox. H302 Harmful if swallowed
<b>Hazard Pictograms:</b>	GHS02, GHS07
<b>Signal Word:</b>	WARNING
<b>Hazard Statements:</b>	Flammable liquid and vapor Harmful if swallowed
<b>Precautionary Statements:</b>	Keep away from heat/sparks/open flames/hot surfaces. No smoking. Wear protective gloves/eye protection. Wear protective clothing. Avoid breathing vapors. IF SWALLOWED: Call a doctor if you feel unwell. Dispose of contents/container in accordance with local, regional, national, international regulations
<b>Other Hazards:</b>	Material should only be used with extreme caution in individuals who may have control over their swallowing reflex. (i.e preschool children and the disabled) Use only for intended scope of application.
<b>Results of PBT and vPvB assessment</b>	PBT: Not applicable vPvB: Not applicable.

## SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical Characterization:** Mixture

**Description:** Mixture of the substances listed below with non-hazardous additions.

Component	CAS No.	Percent by Weight
Ethanol	64-17-5	10-25%
Sodium Fluoride	7681-49-4	2.5-5 %

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

## SECTION 4 – FIRST AID MEASURES

<b>Eye Contact:</b>	Rinse opened eye for several minutes under running water.
<b>Ingestion</b>	Swallowing of larger amounts can lead to nausea, vomiting and/or diarrhea. Immediately call a doctor.
<b>Inhalation:</b>	Supply fresh air; consult doctor in case of complaints.
<b>Skin Contact:</b>	Generally the product does not irritate the skin.
<b>Symptoms and effects (acute and delayed):</b>	No further relevant information available
<b>Immediate Medical Attention/Special Treatment:</b>	No further relevant information available

## SECTION 5 – FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	CO <sub>2</sub> , extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
<b>Specific Hazards During Fire Fighting:</b>	No further relevant information available
<b>Advice for Fire-Fighters:</b>	No further relevant information available

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions:</b>	Wear protective equipment. Keep unprotected persons away.
<b>Environmental Precautions:</b>	Do not allow to enter sewers/surface or ground water.
<b>Clean Up/Containment Methods:</b>	Pick up mechanically. Do not flush into sewer or allow into waterways. Use appropriate Personal Protective Equipment (PPE).

*See Section 7 for information on safe handling*

*See Section 8 for information on personal protective equipment*

*See Section 13 for disposal information*

## SECTION 7 – HANDLING & STORAGE

<b>Precautions for Safe Handling:</b>	For dental use only. Keep ignition sources away. Do not smoke.
<b>Conditions for Safe Storage:</b>	Do not store together with acids. See storage instructions on package. Keep receptacle tightly sealed.

## SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

**Control Parameters:** Components with limit values that require monitoring in the workplace

64-17-5 Ethanol (10-25%)			
PEL	Long-term value:	1900 mg/m <sup>3</sup>	1000 ppm
REL	Long-term value:	1900 mg/m <sup>3</sup>	1000 ppm
TLV	Short-term value:	1880 mg/m <sup>3</sup>	1000 ppm

**Personal Protection**

<b>General Protective and Hygienic Measures::</b>	The usual precautionary measures for handling chemicals should be followed
<b>Hand Protection:</b>	Not required
<b>Respiratory Protection:</b>	Not required

**SECTION 9 – PHYSICAL & CHEMICAL PROPERTIES**

<b>Appearance:</b>	Fluid
<b>Color:</b>	Colorless
<b>Odor:</b>	Fruit-like
<b>pH:</b>	Not determined
<b>Melting Point/Melting Range:</b>	Undetermined
<b>Boiling Point/Boiling Range:</b>	Undetermined
<b>Flash Point:</b>	36°C (97 °F)
<b>Auto-Ignition Temperature:</b>	Product is not self-igniting
<b>Danger of Explosion:</b>	Product does not present an explosion hazard
<b>Relative Density:</b>	At 20°C, 1.02 g/cm <sup>3</sup> (8.512 lbs/gal)
<b>Solubility(ies):</b>	Not miscible or difficult to mix
<b>Viscosity:</b>	Not available

**SECTION 10 – STABILITY & REACTIVITY**

<b>Reactivity:</b>	None known
<b>Chemical Stability:</b>	Stable
<b>Thermal Decomposition/Conditions to be Avoided:</b>	No decomposition if used according to specifications
<b>Hazardous Reactions:</b>	Contact with acids releases toxic gases.
<b>Conditions to Avoid:</b>	No further relevant information is available.
<b>Incompatible Materials:</b>	Avoid oxidizing agents and strong acids
<b>Decomposition Products:</b>	No dangerous decomposition products known.

**SECTION 11 – TOXICOLOGICAL INFORMATION****Toxicological Effects: Acute Toxicity::**

<b>Component</b>	<b>LD<sub>50</sub> (oral)</b>	<b>LD<sub>50</sub> (dermal)</b>	<b>LC<sub>50</sub> (inhalation)</b>
7681-49-4 sodium fluoride	52 mg/kg rat	Not available	Not available

**Carcinogenic Categories:**

IARC  
(International Agency for the Research of Cancer)

The components of 64-17-5 Ethanol is listed by IARC as Group 1 but in alcoholic beverage consumption only. This product is not an alcoholic beverage.

fumed silica  
7681-49-4 sodium fluoride 3

NTP (National Toxicological Program)  
OSHA  
(Occupational Safety and Health Administration).

None of the ingredients is listed  
None of the ingredients is listed

## SECTION 12 – ECOLOGICAL INFORMATION

<b>Aquatic Toxicity:</b>	No further relevant information available.
<b>Persistence and Degradability:</b>	No further relevant information available.
<b>Bioaccumulation:</b>	No further relevant information available.
<b>Mobility in Soil:</b>	No further relevant information available.
<b>General Notes:</b>	Water hazard class 1 (self –assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
<b>Results of PBT and vPvB Assessment:</b>	
<b>PBT:</b>	Not applicable.
<b>vPvB:</b>	Not applicable.
<b>Other Adverse Effects:</b>	No further relevant information available.

## SECTION 13 – DISPOSAL CONSIDERATIONS

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of contents/container in accordance with applicable local, regional, national, and/or international regulations.

## SECTION 14 – TRANSPORT INFORMATION

<b>UN Number:</b> DOT, ADR, IMDG, IATA	UN1170
<b>UN Proper Shipping Name(s):</b> DOT ADR IMDG IATA	Ethanol 1170 Ethanol (Ethyl Alcohol) ETHANOL (ETHYL ALCOHOL) ETHANOL
<b>Transport Hazard Class(es):</b> DOT	
	Class: 3 Flammable liquids
	Label: 3
ADR IMDG IATA	
	Class: 3 Flammable liquids
	Label: 3
<b>Packaging Group:</b> DOT, ADR, IMDG, IATA	III
<b>Environmental Hazards:</b> <b>Marine Pollutant</b>	No
<b>Special Precautions for User:</b>	Warning: Flammable liquids
<b>Danger Code (Kemler):</b>	30
<b>EMS Number:</b>	F-E, S-D
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b>	Not applicable
<b>UN “Model Regulation”:</b>	IN1170, Ethanol (Ethyl Alcohol), 3, III

--	--

## SECTION 15 – REGULATORY INFORMATION

<b>Section 355 (extremely hazardous substances):</b>	None of the ingredients are listed
<b>Section 313 (Specific toxic chemical listings):</b>	None of the ingredients are listed
<b>TSCA Status:</b>	Contact Crosstex for more information. All ingredients are listed
<b>Proposition 65</b>	
<i>Chemical known to cause cancer</i>	None of the ingredients are listed
<i>Chemical known to cause reproductive toxicity for females</i>	None of the ingredients are listed
<i>Chemical known to cause reproductive toxicity for males</i>	None of the ingredients are listed
<i>Chemical known to cause developmental toxicity:</i>	64-17-5 Ethanol
<b>Carcinogenicity Categories</b>	
<i>EPA (Environmental Protection Agency)</i>	None of the ingredients are listed
<i>TLV (threshold Limit Value established by ACGIH)</i>	64-17-5 ethanol A3 7681-49-4 sodium fluoride A-4
<i>NIOSH-Ca (National Institute for Occupational Safety and Health)</i>	None of the ingredients are listed
<i>OSHA-Ca (Occupational Safety &amp; Health Administration)</i>	None of the ingredients are listed
<b>Canadian Substance Listings</b>	
<i>DSL (Canadian Domestic Substance List)</i>	All ingredients are listed
<i>Canadian Ingredient Disclosure limit (limit 0.1%)</i>	Contact Crosstex for more information
<i>Canadian Ingredient disclosure list (limit 1%)</i>	7681-49-4 sodium fluoride

<b>GHS Label Elements:</b>	The product is classified and labeled according to the Globally Harmonized System (GHS)
<b>Hazards pictograms:</b>	GHS02, GHS07
<b>Signal Word:</b>	Warning
<b>Hazard Statements:</b>	Flammable liquid and vapor Harmful if swallowed
<b>Precautionary Statements</b>	Keep away from heat/sparks/open flames/hot surfaces. No smoking. Wear protective gloves/eye protection. Wear protective clothing. Avoid breathing vapors. IF SWALLOWED: Call a doctor if you feel unwell. Dispose of contents/container in accordance with local, regional, national, international regulations.

## SECTION 16 – OTHER INFORMATION

The information contained in this document is correct to the best of our knowledge and is based on current information at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release. Crosstex makes no guarantees or warranty to the validity, accuracy, or currency and shall not be liable or responsible in any way for use of either this information or the materials described.

## Safety Data Sheet

### SECTION 1: IDENTIFICATION

**Product Identifier**

Product Name: Sparkle V® 5% Sodium Fluoride Varnish with Xylitol

**Other Means of Identification**

Product Item Code(s): UFVBG and UFVM

**Recommended use of the chemical and restriction on use**

Recommended Use: Dental Product

Restrictions on Use: For use by dental professional only

**Name, address, telephone number of the supplier:**

Company Address: Crosstex  
6789 W. Henrietta Road  
Rush, New York 14543  
800-722-1529

**Emergency Phone Numbers:**

INFOTRAC:  
24-Hour Number: 1-800-535-5053  
International: +1-352-323-3500

### SECTION 2: HAZARD(S) IDENTIFICATION

**GHS Classification**

- Flammable liquid category 2.
- Acute Toxicity category 3.
- Eye Irritant category 2.
- Skin Sensitizer category 1.

**Signal Word:** Danger

**Hazard Statements:**

H225: Highly flammable liquid and vapor.

H302: Harmful if swallowed.

H319: Causes serious eye irritation.

**Pictograms:**

Flammable Harmful  
Irritant

**Precautionary Statements:**

P210: Keep away from heat. Sparks, open flames, and hot surfaces. No smoking.

P102: Keep out of the reach of children.

P264: Wash hands thoroughly after handling.

**Hazards not otherwise classified:** None

**Unknown Acute Toxicity:** No ingredient with unknown toxicity.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No./ EINECS No.	Percent (By Weight)
Ethanol	64-17-5/200-578-6	20-35%
Sodium Fluoride	7681-49-4/231-667-8	4-6%
Synthetic Resin	68990-02-3/273-574-5	50-70%

### SECTION 4: FIRST AID MEASURES

**Eye Contact:** Flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get medical attention if irritation develops or persists.

**Skin Contact:** Wash skin with plenty of soap and water. Get medical attention if irritation develops.

**Ingestion:** Do not induce vomiting. If conscious, rinse out mouth with water and give copious amounts of milk, or water if milk is not available. Never give anything by mouth to an unconscious person. If symptoms persist, get immediate medical attention.

**Inhalation:** Move victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if irritation persists.

**Most Important symptoms/effects, acute and delayed:**

May cause eye and skin irritation. May cause skin sensitization. May be harmful if swallowed.

**Indication of immediate medical attention and special treatment needed:**

No information available.

### SECTION 5: FIRE FIGHTING MEASURES

**Extinguishing Media:** Use media appropriate for surrounding fire.

**Specific hazards arising from the chemical:** Highly flammable liquid and vapor.

**Special Protective equipment and precautions for firefighters:** Firefighters should wear full emergency equipment and positive pressure self-contained breathing apparatus.

**Unusual Fire/Explosion Hazards:** None under normal conditions of use.

**Known or Anticipated Hazardous Products of Combustion:** Carbon monoxide, carbon dioxide and toxic fumes.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures:** Avoid contact with eyes, skin and clothing. Use appropriate protective equipment as described in Section 8.

**Environmental Precautions:** Prevent spill from entering waterways.



**Methods and materials for containment and cleaning up:** Wipe up or collect using an inert absorbent material and place in appropriate containers for disposal. Rinse spill area with water. Prevent spill from entering sewers and water courses. Report releases as required by local, state and federal authorities.

## SECTION 7: HANDLING AND STORAGE

**Precautions for safe handling:** Avoid contact with the eyes, skin and clothing. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers tightly closed when not in use.

Do not reuse containers. Empty containers retain product residues that can be hazardous. Follow all safety precautions when handling empty containers.

**Conditions for safe storage including any incompatibilities:** Store in a cool, dry, well-ventilated area. Do not store above 25°C (77°F). Keep out of direct sunlight. Keep away from heat and ignition sources. Keep out of reach of children.

## SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

**Exposure Control Parameters:** The parameters are not provided for the product itself. They are provided for the ingredients listed below:

### **Occupational Exposure Limits:**

Sodium Fluoride (as Fluoride)	2.5mg/m <sup>3</sup> TWA ACGIH 2.5mg/ m <sup>3</sup> TWA OSHA
Ethanol	1000 ppm STEL ACGIH 1900 mg/m <sup>3</sup> TWA OSHA

**Appropriate Engineering Controls:** No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits.

### **Individual Protection Measures:**

#### **Personal Protective Equipment**

**Eye Protection:** Safety glasses recommended.

**Skin Protection:** Wear impervious gloves.

**Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded an approved respirator with particulate cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.

**Other Protective Clothing or Equipment:** None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance:** Off white to yellow colored liquid.

**Odor:** Characteristic

**Odor Threshold:** Not available

**pH:** Not available

**Melting Point:** Not applicable

**Freezing Point:** Not available

**Boiling Point/Range:** Not available

**Flashpoint:** Not available

**Evaporation Rate:** Not available

**Flammability (solid, gas):** Not available

**Upper/lower flammability or explosive limits:**

LEL: Not available

UEL: Not available

**Vapor Pressure:** Not available

**Vapor Density:** Not available

**Relative Density:** Not available

**Solubility in water:** Slightly soluble

**Partition coefficient (n-octanol/water):** Not available

**Autoignition Temperature:** Not available

**Decomposition Temperature:** Not available

**Viscosity:** Not available

**SECTION 10: STABILITY AND REACTIVITY**

**Reactivity:** None known

**Chemical Stability:** Stable

**Possibility of Hazardous Reactions:** None under normal conditions of use

**Conditions to Avoid:** Keep away from ignition sources.

**Incompatible Materials:** Avoid oxidizing agents and strong acids.

**Hazardous Decomposition Products:** May produce carbon monoxide, carbon dioxide and toxic fumes.

**SECTION 11: TOXICOLOGICAL INFORMATION****Information on Toxicological Effects**

Toxicological data not available for the product itself. The data provided are for the ingredients listed below.

Sodium Fluoride: Oral rat LD<sub>50</sub>: 52 mg/kg

Ethanol: Oral rat LD<sub>50</sub>: 7060 mg/kg

**Likely Routes of Exposure and the Symptoms related to the Physical, Chemical and Toxicological****Characteristics:**

**Eyes:** Direct contact causes eye irritation.

**Skin:** Prolonged skin contact may cause irritation.

**Inhalation:** No adverse effects expected, under normal conditions of use.

**Ingestion:** May cause salivation, nausea, vomiting, abdominal pain, headaches, or dizziness.

**Chronic Health Effects:** Not expected under normal conditions of use. Repeated overexposure to Sodium Fluoride may cause fluorosis.

**Mutagenicity:** No data available.

**Carcinogenicity:** Not known to be as carcinogen or potential carcinogen by NTP (National Toxicological Program), IARC (International Agency for the Research of Cancer) or OSHA (Occupational Safety and Health Administration).

**Medical Conditions Aggravated by Exposure:** Individuals with pre-existing skin disease may be at increased risk from exposure.

<b>SECTION 12: ECOLOGICAL INFORMATION</b>
---

**Eco toxicity**

Ecological data not available for the product itself. The data provided are for the ingredients listed below:

Sodium Fluoride: 96 hrs. LC<sub>50</sub> fish: >100 mg/L

Ethanol: 96 hrs. LC<sub>50</sub> rainbow trout: >10,000 mg/L

**Persistence and degradability**

No information available

**Bioaccumulative Potential:** No data available

**Mobility in soil:**

No data available

**Other adverse effects:**

No information available

<b>SECTION 13: DISPOSAL CONSIDERATIONS</b>
--

Dispose in accordance with national and local regulations.

<b>SECTION 14: TRANSPORT INFORMATION</b>
--

\*Please refer to your local, state and national transport regulations as limited quantity exceptions may apply for the product as supplied, before the use of the information provided in this section.

DOT (US)

Proper Shipping Name: Ethanol solutions

Hazard Class: 3

UN Number: UN 1170  
Packing Group: II  
Air (IATA/ICAO)  
Proper Shipping Name: Ethanol solutions  
Hazard Class: 3  
UN Number: UN 1170  
Packing Group: II  
IMO/IMDG  
Proper Shipping Name: Ethanol solutions  
Hazard Class: 3  
UN Number: UN 1170  
Packing Group: II

## SECTION 15: REGULATORY INFORMATION

### U.S. FEDERAL REGULATIONS:

#### SARA TITLE III:

**Hazard Category for Section 311/312:** Acute Health, Fire Hazard.

**Section 313 Toxic Chemicals:** This product contains the following chemicals subject to Annual Release Reporting Requirements under SARA Title III, Section 313 (40 CFR 372): None at or above reportable quantity.

**Section 302 extremely hazardous Substances (TPQ):** None at or above reportable quantity

**EPA Toxic Substances Control Act (TSCA) Status:** This product is a medical device and not subject to chemical notification requirements.

Note: The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the safety data sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

## SECTION 16: OTHER INFORMATION

Risk phrases used in Section 2:

- H225: Highly flammable liquid and vapor.
- H302: Harmful if swallowed.
- H319: Causes serious eye irritation.

Legal disclaimer: The information contained in this document is correct to the best of our knowledge and is based on current information at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release. Crosstex makes no guarantees or warranty to the validity, accuracy, or currency and shall not be liable or responsible in any way for use of either this information or the materials described.