

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 International
10 Ranick Road
Hauppauge, New York
11788
631.582.6777

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 ³ TWA ACGIH 2.5mg/ m ³ TWA OSHA
Ethanol	1000 ppm STEL ACGIH 1900 mg/m ³ 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 LD₅₀: 52 mg/kg

Ethanol: Oral rat LD₅₀: 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.

SECTION 12: ECOLOGICAL INFORMATION

Eco toxicity

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

Sodium Fluoride: 96 hrs. LC₅₀ fish: >100 mg/L

Ethanol: 96 hrs. LC₅₀ 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

SECTION 13: DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14: TRANSPORT INFORMATION

*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.

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