

Safety Data Sheet

FluoriMax 2.5% NaF Varnish

Section 1 - Identification

Product Name:	FluoriMax 2.5% Sodium Fluoride Varnish
Synonyms:	Fluoride varnish, varnish
Flavors:	Bubble Gum, Mint, Salted Caramel, Cotton Candy, & Unflavored
Active Ingredient:	Sodium Fluoride
Company Identification:	Elevate Oral Care 346 Pike Rd Suite 5 West Palm Beach, FL 33411
Issue Date:	01/04/2013
For information, call:	Elevate Oral Care, 877-866-9113
Emergency Number:	Poison Control Center 800-222-1222
Product Use:	Dental, for use as a Fluoride Varnish
Limitations:	For use by Dental Professionals

Section 2 - Hazards Identification

Emergency Overview

This information is based on findings from related and/or similar materials.

Please read the entire MSDS for additional information.

Product contains ethanol.

Potential Health Effects, Signs, Symptoms of Exposure:

Signal Word: Danger

Danger Symbols: GHS02, GHS06, GHS07, GHS08



Hazard Statements: H320, H316, H333, H335, H303

Prolonged or repeated exposure may cause:

Eye: Splashing into the eye may cause moderate irritation. Symptoms may include redness, swelling, pain, tearing, and blurred or hazy vision.

Skin: Contact with skin may cause moderate irritation to the skin. Symptoms may include localized redness, swelling, itching, and dryness.

Inhalation: Respiratory tract irritation. Symptoms may include cough, sneezing, nasal discharge, headache, hoarseness, and nose and throat pain.



Respiratory Effects: Signs/symptoms may include cough, shortness of breath, chest tightness, wheezing, increased heart rate, bluish colored skin (cyanosis), sputum production, changes in lung function tests, and/or respiratory failure. May be absorbed following inhalation and cause target organ effects.

Ingestion: May be harmful if swallowed. Gastrointestinal Irritation: Signs/symptoms may include abdominal pain, upset stomach, nausea, vomiting and diarrhea.

Carcinogenicity: This product contains ethanol. Alcoholic beverages have been classified as human carcinogens by the International Agency for Research on Cancer, the U.S. National Toxicology Program, and the California Environmental Protection Agency (for purposes of Proposition 65). Exposure to ethanol during the foreseeable use of this product is not expected to cause cancer.

Please refer to Section 16 for Hazard and Precautionary Statement Key.

Section 3 - Composition, Information on Ingredients

Chemical ID	CAS-No	% (By Weight) *
Ethyl Alcohol, 200 proof	64-17-5	>10%
Sodium Fluoride	7681-49-4	<5%
Premium Shellac	9000-59-3	>10%
Propylene Glycol	57-55-6	>5%
Disodium Phosphate Anhydrous	7558-79-4	<5%
Xylitol	87-99-0	<5%
Sucralose	56038-13-2	<5%
Flavoring:		
<i>Mint Flavor</i>	N/A	<5%
<i>Bubble Gum Flavor</i>	N/A	<5%
<i>Caramel Cream Flavor</i>	N/A	<5%
<i>Bitterness Masking Type Flavor</i>	N/A	<5%
<i>Cotton Candy Flavor</i>	N/A	<5%

*The exact concentration is being withheld as a trade secret.

Sodium Fluoride: **Signal word: Danger**

Danger symbols: GHS06, GHS07

Hazard statements: H301, H315, H319

Precautionary statements: P264, P270, P280, P301+310+330, P302+352, P305+351+338, P332+313, P337+313, P362, P405, P501




Shellac**Signal word: Danger**

Germ cell mutagenicity: Category 1

Toxic to reproduction: Category 1

Specific target organ systemic toxicity: Category 2 (Liver) (Repeated Exposure)

Danger symbols: GHS08 

Hazard statements: H340, H360, H373

Precautionary statements: P201, P202, P280, P260, P405, P308+313, P314, P501

Ethyl Alcohol:**Signal word: Danger**

Group 1: Carcinogenic to humans IARC

100% of the mixture consists of component(s) of unknown acute toxicity.

Flammable liquids – Category 2

Acute toxicity, inhalation – Category 3

Serious eye damage/eye irritation – Category 2A

Danger symbols: GHS02, GHS06, GHS07   


Hazard Statements: H225, H331, H319

Precautionary Statements: P210, P233, P240, P241, P242, P243, P261, P264, P271, P280, P303+P361+P353, P304+340, P305+351+338, P311+337+P313, P370+378.

Flavors**Bubble Gum:****Signal word: Danger**Danger symbols: GHS02, GHS07  


Hazard statements: H225, H315, H317, H319, H332

Precautionary statements: P210, P233, P261, P280, P362, P302+352, P305+351+338, P312, P333+313, P337+313, P240, P241, P242, P243, P363

Mint:**Signal word: Warning**Danger symbol: GHS07 

Hazard statements: H227, H302, H332

Precautionary statements: P210, P280, P270

Cotton Candy:**Signal word: Warning**Danger symbol: GHS07 

Hazard statements: H320, H317, H336

Precautionary statements: P261, P280, P302+352, P333+313



Section 4 - First Aid Measures

The following first aid recommendations assume that appropriate personal hygiene and industrial hygiene practices are followed.

- General Advice:** Do not leave the victim unattended.
- Eye Contact:** Flush eyes with large amounts of water, including under eyelids. If signs/symptoms persist, get medical attention.
- Skin Contact:** Remove contaminated clothing and shoes. Immediately flush skin with large amounts of water. Get medical attention if needed. Wash contaminated clothing and clean shoes before reuse.
- Inhalation:** Remove person to fresh air. If signs/symptoms develop, get immediate medical attention.
- If Swallowed:** Do not induce vomiting, give victim two glasses of water. Never give anything by mouth to an unconscious person. Get immediate medical attention.
- Physician Notes:** Treat symptomatically.

Section 5 - Fire Fighting Measures

Extinguishing Media: Use fire extinguishers with class B extinguishing agents (e.g., dry chemical, carbon dioxide).

Protection of Fire Fighters

Special Fire Fighting Procedures: Water may not effectively extinguish fire; however, it should be used to keep fire-exposed containers and surfaces cool and prevent explosive rupture. Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).

Unusual Fire and Explosion Hazards: Flammable liquid and vapor. Closed containers exposed to heat from fire may build pressure and explode.

Section 6 - Accidental Release Measures

Personal Precautions, Protective Equipment, and Emergency Procedures

Evacuate unprotected and untrained personnel from hazard areas. The spill should be cleaned up by qualified personnel. Cover, but do not seal for 48 hours.

**Environmental Precautions:**

For larger spills, cover drains and build dikes to prevent entry into sewer systems or bodies of water. Place in a metal container approved for use in transportation by appropriate authorities. The container must be lined with polyethylene plastic or contain a plastic drum liner made of polyethylene.

Clean-up methods:

Observe precautions from other sections. Determine if spill qualifies for local, state, or federal reporting.

Section 7 - Handling and Storage

Handling:

Keep away from heat, sparks, open flames, pilot lights and other sources of ignition. Avoid breathing of vapors, mists, or spray. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures below Occupational Exposure Limits. If ventilation is not adequate, use respiratory protection equipment. Avoid eye contact. Avoid prolonged or repeated skin contact. Wash hands after handling and before eating.

Storage:

Store at controlled room temperature $23^{\circ}\text{C} \pm 2^{\circ}\text{C}$ in a well-ventilated area away from freezing, heat, sparks, and flames. Keep containers closed when not in use. Keep in original container provided by manufacturer.

Section 8 - Exposure Controls/Personal Protection

Exposure Guidelines

No exposure standards have been established for this product, however, the Occupational Safety & Health Administration (OSHA) exposure standards for the following materials are as follows:

Chemical Name	CAS-No	OSHA PEL
Sodium Fluoride	7681-49-4	2.5 mg/m ³
Ethyl Alcohol	64-17-5	1900 mg/m ³ 1000 ppm
Propylene Glycol	57-55-6	10 mg/m ³
Sucralose	56038-13-2	15 mg/m ³ - Total dust 5 mg/m ³ - Respirable dust
Hydroxyapatite	12167-74-7	3.04 mg/m ³ inhalation

No relevant exposure guidelines for other ingredients.

Engineering Controls: Use with appropriate local exhaust ventilation, or in a well-ventilated area.

Personal Protective Equipment (PPE)

Eye/Face Protection: Avoid eye contact. The following eye protection is recommended: Safety Glasses



Skin Protection: Avoid prolonged or repeated skin contact. Gloves not normally required.

Respiratory Protection: Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection. Avoid breathing vapors, mists, or spray.

Prevention of Swallowing: Do not ingest. Wash hands after handling and before eating.

Section 9 - Physical and Chemical Properties

Appearance/physical form	Odor	Solubility in water	Viscosity	Specific Gravity
Amber liquid	Consistent with label stated flavor	NDA	50 - 500	0.95 – 1.00

Lower/Upper Explosive Limits	Melting Point	Flash Point	Boiling Point
Not Determined	N/A	NDA	NDA

Section 10 - Stability and Reactivity

Stability: Stable.

Materials and Conditions to Avoid: Heat, sparks, open flame.

Materials to Avoid: Strong oxidizing agents, Strong acids.

Hazardous Polymerization: Hazardous polymerization will not occur.

Hazardous Decomposition or By-Products

Substance	Condition
Carbon monoxide	During Combustion
Carbon dioxide	During Combustion

Section 11 - Toxicology Information

Hazardous ingredients:

Ethanol
IVN RAT LD50 1440 mg/kg
ORL MUS LD50 3450 mg/kg
ORL RAT LD50 7060 mg/kg



Sodium Fluoride

ORL MUS LD50 57 mg/kg
ORL RAT LD50 52 mg/kg
SCU RAT LD50 175 mg/kg

Premium Shellac

ORL HUM LDLO 1400 mg/kg
ORL RAT LD50 7080 mg/kg
INH RAT LC50 20000 ppm/10h

Section 12 - Ecological Information

Ecotoxicity: Not Determined
Chemical Fate: Not Determined
Physical: No information available
Other: No information available.
Mobility: Readily absorbed into soil
Persistence and degradability: Biodegradable
Bio accumulative potential: No bioaccumulation potential

Section 13 - Disposal Considerations

Waste Disposal Method: Incinerate uncured product in a permitted hazardous waste incinerator. As a disposal alternative, dispose of waste product in a permitted hazardous waste facility. Follow local, regional, state, and national guidelines.

RCRA P-Series: None listed.

RCRA U-Series: None listed.

Section 14 - Transportation Information

	US DOT
Shipping Name:	FLAMMABLE LIQUID, N.O.S.
Hazard Class:	3
UN Number:	1993
Packing Group:	II

Meets 49 CFR 173.150 (g)1. I requirements for Exceptions for Class 3 (flammable and combustible liquids).

Section 15 - Regulatory Information

US Federal

TSCA: CAS# 64-17-5 is listed on the TSCA inventory.

SARA Codes: CAS# 64-17-5: acute, chronic, flammable.

311/312 Hazard Categories: Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No Immediate Hazard - Yes Delayed Hazard – Yes

State

CAS# 64-17-5 can be found on the following state right to know lists: California, New Jersey, Pennsylvania, Minnesota, Massachusetts.

California Prop 65

WARNING: This product contains Ethanol, a chemical known to the state of California to cause developmental reproductive toxicity.

California No Significant Risk Level: None of the chemicals in this product are listed.

European/International Regulations

European Labeling in Accordance with EC Directives

Section 16 - Other Information



European
Community:

DANGER SYMBOLS: **GHS07 (Xi)** – *Warning/Irritant*
HAZARD STATEMENTS: **H302**, Harmful if swallowed; **H315**, causes skin irritation; **H319**, Causes serious eye irritation.
Precautionary Statements: See Section 16

EU Classes and Risk/Safety Phases for Referenced Ingredients (See Section 2)

Danger Symbols:

GHS02 – Flammables



GHS06 – Danger/Toxic



GHS07 – Warning/Irritant



GHS08 – Health Hazard





Hazard Statements:

H225 – Highly flammable liquid and vapor.
H227 – Combustible liquid.
H301 – Toxic if swallowed.
H302 – Harmful if swallowed.
H303 – May be harmful if swallowed.
H304 – May be fatal if swallowed and enters airways.
H305 – May be harmful if swallowed and enters airways.
H311 – Toxic in contact with skin.
H314 – Causes severe skin burns and eye damage.
H315 – Causes skin irritation.
H316 – Causes mild skin irritation.
H317 – May cause an allergic skin reaction.
H319 – Causes serious eye irritation.
H320 – Causes eye irritation.
H331 – Toxic if inhaled.
H332 – Harmful if inhaled.
H333 – May be harmful if inhaled.
H335 – May cause respiratory irritation.
H336 – May cause drowsiness or dizziness.
H340 – May cause genetic defects.
H351 – Suspected of causing cancer.
H360 – May damage fertility or the unborn child.
H373 – May cause damage to organs through prolonged or repeated exposure.

R25 – Harmful if swallowed.
R32 – Contact with acids liberates toxic gas.
R36/37/38 – Irritating to eyes, respiratory system, and skin.

Precautionary Statements:

P102 – Keep out of reach of children.
P201 – Obtain special instructions before use.
P202 – Do not handle until all safety precautions have been read and understood.
P210 – Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.
P220 – Keep/store away from clothing...combustible materials.
P221 – Take any precaution to avoid mixing with combustibles.
P233 – Keep container tightly closed.
P240 – Ground/bond container and receiving equipment.
P241 – Use explosion-proof electrical/ventilating/lighting/.../equipment.
P242 – Use only non-sparking tools.
P243 – Take precautionary measures against static discharge.
P260 – Do not breathe dust/fumes/gas/mist/vapors/spray.

P261 – Avoid breathing dust/fumes/gas/mist/vapors/spray.
P370+378 – In case of fire: use...to extinguish.
P264 – Wash hands after use, rinse oral cavity and expectorate fluid.
P270 – Do not eat, drink, or smoke while 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/face protection.
P303 – IF ON SKIN:
P304 – IF INHALED:
P305 – IF IN EYES:
P308+313– If exposed or concerned get medical advice/attention.
P311 – Call a POISON CENTER/doctor/...
P312 – Call a poison center/doctor if you feel unwell.
P314 – Get medical advice/attention if you feel unwell.
P321 – Specific treatment (see...on this label)
P330 – Rinse mouth.
P331 – DO NOT induce vomiting.
P301+310 – IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P301+P312 – IF SWALLOWED: Call a POISON CENTER or a medical professional if you feel unwell.
P302+P352 – IF ON SKIN: Wash with plenty of water.
P332+313 – If skin irritation occurs get medical advice/attention.
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
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 advice/attention.
P338 – Remove contact lenses if present, and easy to do. Continue rinsing.
P309+314 (S45) – If exposed, or you feel unwell, seek medical advice/attention.
P304+340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P351 – Rinse cautiously with water for several minutes.
P353 – Rinse skin with water/shower.
P361 – Take off immediately all contaminated clothing.
P362 – Take off contaminated clothing.
P363 – Wash contaminated clothing before reuse.
P370+378 – In case of fire: Use...to extinguish.



P403+233 – Store in a well-ventilated place. Keep container tightly closed.

P403+235 – Store in a well-ventilated place. Keep cool.

P405 – Store locked up.

P501 – Dispose of contents/container in accordance with local/state/national/international regulation.

	Health Hazard	Flammability	Reactivity
NFPA:	1	1	1
HMIS	1	1	1

MSDS Creation Date: 01/04/2013

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Disclaimer:

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