

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 1 of 7

MATERIAL SAFETY DATA SHEET**SECTION 1 - IDENTIFICATION**

Product identifier : **2.72% Topical Sodium Fluoride Foam**

Product Code(s) : 10037-All Flavors

Product Use : Topical anti-caries preparation.

Chemical Family : Mixture

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SECTION 2 - HAZARDS IDENTIFICATION

Classification : WHMIS information: This product is not a WHMIS controlled product in Canada. This product is a Drug Product and is therefore not regulated as a Controlled Product under the Hazardous Products Act (HPA).

OSHA: This product is regulated under the Food and Drugs Act as a Drug product.

Emergency Overview : White foam in a pressurized container. Characteristic odour. Caution! This product may be combustible at high temperatures. May cause mild skin irritation. May cause moderate eye irritation. May cause irritation to the mouth, throat and stomach. May cause irritation to upper respiratory system. Prolonged exposure may cause skeletal fluorosis (weakened bone structure).

POTENTIAL HEALTH EFFECTS:**Signs and symptoms of short-term (acute) exposure**

Inhalation : May cause irritation to the nose, throat and upper respiratory tract. Exposure to high vapour concentration can cause dizziness, nausea and central nervous system depression.

Skin : May cause mild skin irritation.

Eyes : May cause moderate eye irritation.

Ingestion : Irritation of the mouth, throat, esophagus, and stomach. Toxic effects may occur from swallowing excessive amounts.

Effects of long-term (chronic) exposure

: Prolonged or repeated skin contact may cause defatting and drying resulting in irritation and possible dermatitis.

Carcinogenic status : See TOXICOLOGICAL INFORMATION, Section 11.

Additional health hazards : See TOXICOLOGICAL INFORMATION, Section 11.

Potential environmental effects

: See ECOLOGICAL INFORMATION, Section 12.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredients</u>	CAS #	Wt.%

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 2 of 7

Sodium fluoride	7681-49-4	1.00 - 5.00
Hydrogen fluoride	7664-39-3	0.10 - 1.00
Isobutane	75-28-5	5.00 - 10.00
Propane	74-98-6	5.00 - 10.00

SECTION 4 - FIRST AID MEASURES

- Inhalation** : Immediately remove person to fresh air. If breathing has stopped, give artificial respiration. If breathing is difficult, give oxygen by qualified medical personnel only. Get medical attention.
- Skin contact** : Wash exposed area thoroughly with soap and water for at least 15 minutes. Get medical attention if irritation develops and persists.
- Eye contact** : Flush with large amounts of water for 15 minutes. Get medical attention if irritation develops and persists.
- Ingestion** : Do not induce vomiting, unless directed to do so by qualified medical personnel. Have victim drink milk to decrease absorption. Seek immediate medical attention/advice.
- Notes For Physician** : Treat symptomatically.

SECTION 5 - FIRE FIGHTING MEASURES

Fire hazards/conditions of flammability

- : Not flammable under normal conditions of use. Closed containers are contained under pressure and may explode if exposed to excess heat for a prolonged period of time.

Flammability classification (OSHA 29 CFR 1910.1200)

- : Combustible Liquid Class III B.

Oxidizing properties

- : None known.

Explosion data: Sensitivity to mechanical impact / static discharge

- : Not expected to be sensitive to mechanical impact or static discharge.

Suitable extinguishing media

- : Use media suitable to the surrounding fire such as water fog or fine spray, alcohol foams, carbon dioxide and dry chemical.

Special fire-fighting procedures/equipment

- : Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. Move containers from fire area if safe to do so.

Hazardous combustion products

- : Oxides of carbon and nitrogen. Hydrocarbons. Fluorinated products.

NFPA Rating

- 0 - Minimal 1 - Slight 2 - Moderate 3 - Serious 4 - Severe
- : *Health:* 1 *Flammability:* 1 *Instability:* 0 *Special Hazards:* None.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

- Personal precautions** : Restrict access to area until completion of clean-up. Keep all other personnel upwind and away from the spill/release. Individuals involved in the cleanup must wear appropriate personal protective equipment. Refer to protective measures listed in sections 7 and 8.
- Environmental precautions** : Ensure spilled product does not enter drains, sewers, waterways, or confined spaces.
- Spill response/cleanup** : Ventilate area of release. Stop the spill at source if it is safe to do so. Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g. sand), then place absorbent material into a container for later disposal (see Section 13). Notify the appropriate authorities as required.
- Prohibited materials** : None known.
- Special spill response procedures**

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 3 of 7

- : If a spill/release in excess of the EPA reportable quantity is made into the environment, immediately notify the national response center in the United States (phone: 1-800-424-8802).
- US CERCLA Reportable quantity (RQ): Sodium fluoride.

SECTION 7 - HANDLING AND STORAGE

- Safe Handling procedures** : Wear chemically resistant protective equipment during handling. Use only in well-ventilated areas. Do not ingest. Avoid contact with eyes, skin and clothing. Avoid contact with incompatible materials. Keep container tightly closed when not in use. Wash thoroughly after handling. Do not puncture, incinerate or expose to heat even when empty.
- Storage requirements** : Store in a cool, dry, well ventilated area, away from heat and ignition sources. Store away from incompatibles and out of direct sunlight. Storage area should be clearly identified, clear of obstruction and accessible only to trained and authorized personnel. No smoking in the area. Inspect periodically for damage or leaks. Do not store at temperatures over 26.67°C (80°F).
- Incompatible materials** : Strong oxidizing agents; Halogenated compounds
- Special packaging materials** : Always keep in containers made of the same materials as the supply container.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

<u>Exposure Limits</u>				
<u>Ingredients</u>	<u>ACGIH TLV</u>		<u>OSHA PEL</u>	
	<u>TWA</u>	<u>STEL</u>	<u>PEL</u>	<u>STEL</u>
Sodium fluoride	N/Av	N/Av	N/Av	N/Av
Hydrogen fluoride	0.5 ppm (as F)	N/Av	3 ppm (as F)	N/Av
Isobutane	1000 ppm (listed under Aliphatic hydrocarbon gases: Alkane C1-4)	N/Av	N/Av	N/Av
Propane	1000 ppm (listed under Aliphatic hydrocarbon gases: Alkane C1-4)	N/Av	1000 ppm ; 1800 mg/m ³	N/Av

Ventilation and engineering measures

- : Do not use in closed or confined space. Use general or local exhaust ventilation to maintain air concentrations below recommended exposure limits.

Respiratory protection

- : Not required under normal conditions of handling.

Skin protection

- : Solvent-resistant gloves. Advice should be sought from glove suppliers.

Eye / face protection

- : Chemical splash goggles are recommended.

Other protective equipment

- : An eyewash station and safety shower should be made available in the immediate working area. Depending on conditions of use, an impervious apron should be worn. Remove and wash contaminated clothing before re-use.

General hygiene considerations

- : Avoid contact with skin, eyes and clothing. Do not eat, drink, smoke or use cosmetics while working with this product. Upon completion of work, wash hands before eating, drinking, smoking or use of toilet facilities. Remove soiled clothing and wash it thoroughly before reuse.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Paste **Appearance** : Various colours.

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 4 of 7

Odour	: Characteristic odour.	Odour threshold	: N/Av
pH	: 4 - 6		
Boiling point	: N/Av	Specific gravity	: N/Av
Melting/Freezing point	: N/Av	Coefficient of water/oil distribution	: N/Av
Vapour pressure (mmHg @ 20° C / 68° F)	: N/Av	Solubility in water	: soluble
Vapour density (Air = 1)	: N/Av	Evaporation rate (n-Butyl acetate = 1)	: N/Av
Volatile organic Compounds (VOC's)	: N/Av	Volatiles (% by weight)	: N/Av
Flash point	: N/Av		
Flash point Method	: N/Av	Auto-ignition temperature	: N/Av
Lower flammable limit (% by vol.)	: N/Av	Upper flammable limit (% by vol.)	: N/Av
Flame Projection Length	: N/Av	Flashback observed	: N/Av
Viscosity	: Viscous.		
Absolute pressure of container	: N/Av		

Section 10: Stability And Reactivity

Stability and reactivity	: Stable under recommended storage conditions.
Hazardous polymerization	: Hazardous polymerisation does not occur.
Conditions to avoid	: Keep out of direct sunlight. Keep away from excessive heat, open flames, sparks and other possible sources of ignition. Do not use in areas without adequate ventilation.

Materials To Avoid And Incompatibility

: See Section 7 (Handling and Storage) for further details.

Hazardous decomposition products

: Refer to Section 5 for additional 'Hazardous combustion products'.

SECTION 11 - TOXICOLOGICAL INFORMATION

Target organs	: Eyes, skin and digestive system.
Routes of exposure	: <i>Inhalation</i> : YES <i>Skin Absorption</i> : NO <i>Skin & Eyes</i> : YES <i>Ingestion</i> : YES
Toxicological data	: There is no available data for the product itself, only for the ingredients. See below for individual ingredient acute toxicity data.

<u>Ingredients</u>	<u>LC₅₀(4hr)</u> <u>inh, rat</u>	<u>LD₅₀</u>	
		<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Sodium fluoride	N/Av	52 mg/kg	175 mg/kg
Hydrogen fluoride	655 ppm	N/Av	N/Av
Isobutane	658 mg/L 4 h	N/Av	N/Av
Propane	658 mg/L 4 h	N/Av	N/Av

Carcinogenic status	: No components are listed as carcinogens by ACGIH, IARC, OSHA or NTP.
Reproductive effects	: Not expected to cause reproductive effects.
Teratogenicity	: Not expected to be a teratogen.
Mutagenicity	: Not expected to be mutagenic in humans.
Epidemiology	: Not available.
Sensitization to material	: Not expected to be a skin or respiratory sensitizer.
Synergistic materials	: N/Av
Irritancy	: May cause eye and skin irritation. May cause gastrointestinal irritation.
other important hazards	: None known.

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 5 of 7

Conditions aggravated by overexposure

: Pre-existing skin, eye and respiratory disorders.

SECTION 12 - ECOLOGICAL INFORMATION

Ecotoxicity : The product should not be allowed to enter drains or water courses, or be deposited where it can affect ground or surface waters.
 The acute toxicity of sodium fluoride is:
 Toxicity to fish: LC50/96h/rainbow trout = 51 - 108 mg/L
 Toxicity to invertebrates EC50/48h/Daphnia magna (Water flea) = 97 - 153 mg/L
 Toxicity to algae EC50/96h/Skeletonema costatum = 122 mg/L


The acute toxicity of hydrogen fluoride is:
 Toxicity to fish: LC50/96h/Oncorhynchus mykiss (rainbow trout) = 51 - 108 mg/L
 Toxicity to invertebrates EC50/48h/Daphnia magna (Water flea) = 97 - 153 mg/L

Mobility : No data is available on the product itself.
Persistence : No data is available on the product itself.
Bioaccumulation potential : No data is available on the product itself.
Other Adverse Environmental effects : No data is available on the product itself.

SECTION 13 - DISPOSAL CONSIDERATIONS

Handling for Disposal : Handle waste according to recommendations in Section 7.
Methods of Disposal : Improper disposal can cause damage to the environment. Dispose in accordance with all applicable federal, state, provincial and local regulations. Contact your local, state, provincial or federal environmental agency for specific rules.
RCRA : It is the responsibility of the waste generator to determine the proper waste identification and disposal method. For disposal of unused or waste material, check with local, state and federal environmental agencies.

SECTION 14: TRANSPORT INFORMATION

Regulatory Information	UN Number	Shipping Name	Class	Packing Group	Label
TDG	None.	Not regulated.	Not regulated	none	
TDG Additional information	None.				
49CFR/DOT	None.	Not regulated.	Not regulated	none	
49CFR/DOT Additional information	None.				

SECTION 15 - REGULATORY INFORMATION

US Federal Information:

TSCA: All listed ingredients appear on the Toxic Substances Control Act (TSCA) inventory.

CERCLA Reportable Quantity (RQ) (40 CFR 117.302): Sodium fluoride (1000lbs / 454kg).

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 6 of 7

SARA TITLE III: Sec. 302, Extremely Hazardous Substances, 40 CFR 355: No Extremely Hazardous Substances are present in this material.

SARA TITLE III: Sec. 311 and 312, MSDS Requirements, 40 CFR 370 Hazard Classes: Acute Health Hazard. Chronic Health Hazard. Under SARA Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds for the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

SARA TITLE III: Sec. 313, Toxic Chemicals Notification, 40 CFR 372: This product may be subject to SARA notification requirements, since it contains Toxic Chemical constituents above their de minimums concentrations. This product contains: Hydrogen fluoride.

US State Right to Know Laws:

California Proposition 65: To the best of our knowledge, this product does not contain any chemicals known to the State of California to cause cancer or reproductive harm.

Other U.S. State "Right to Know" Lists: The following chemicals are specifically listed by individual States: Sodium Fluoride (MA, NJ, CA, PA, RI), Hydrogen fluoride (MA, MN, NJ, CA, PA, RI); Isobutane (NJ, PA); Propane (MA, MN, NJ, PA, RI).

International Information:

WHMIS information: Refer to Section 2 for a WHMIS Classification for this product.

Canadian Environmental Protection Act (CEPA) information: All ingredients listed appear on the Domestic Substances List (DSL).

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and this MSDS contains all the information required by the CPR.

SECTION 16 - OTHER INFORMATION

HMIS Rating : * - Chronic hazard 0 - Minimal 1 - Slight 2 - Moderate 3 - Serious 4 - Severe
Health: 1 *Flammability:* 1 *Reactivity:* 0

Legend : ACGIH: American Conference of Governmental Industrial Hygienists
CA: California
CAS: Chemical Abstract Services
CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR: Code of Federal Regulations
CNS: Central Nervous System
DOT: Department of Transportation
HMIS: Hazardous Materials Identification System
HSDB: Hazardous Substances Data Bank
IARC: International Agency for Research on Cancer
Inh: Inhalation
LC: Lethal Concentration
LD: Lethal Dose
MA: Massachusetts
MN: Minnesota
MSHA: Mine Safety and Health Administration
N/Ap: Not Applicable
N/Av: Not Available
NFPA: National Fire Protection Association
NIOSH: National Institute of Occupational Safety and Health
NJ: New Jersey
NTP: National Toxicology Program
OSHA: Occupational Safety and Health Administration
PA: Pennsylvania

2.72% Topical Sodium Fluoride Foam

MSDS Preparation Date (mm/dd/yyyy): 07/30/2013

Page 7 of 7

PEL: Permissible exposure limit
RCRA: Resource Conservation and Recovery Act
RI: Rhode Island
RTECS: Registry of Toxic Effects of Chemical Substances
SARA: Superfund Amendments and Reauthorization Act
STEL: Short Term Exposure Limit
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
TLV: Threshold Limit Values
TWA: Time Weighted Average
WHMIS: Workplace Hazardous Materials Identification System

References

- : 1. ACGIH, Threshold Limit Values and Biological Exposure Indices for 2012
- 2. International Agency for Research on Cancer Monographs, searched 2012
- 3. Canadian Centre for Occupational Health and Safety, CC Info Web databases (Chempendium, HSDB and RTECs). (2012)
- 4. US EPA Title III List of Lists (July 2011)
- 5. California Proposition 65 List (16 March 2012)

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