

**2% Neutral Sodium Fluoride Gel**

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

**Product identifier** : **2% Neutral Sodium Fluoride Gel**

**Product Code(s)** : 10023- All flavors

**Product Use** : Topical anti-caries preparation.

**Chemical Family** : Sodium Fluoride

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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** : Paste. Various colours. Characteristic odour.  
Caution! Contact with acids liberates very toxic gas. May cause mild skin irritation. May cause moderate eye irritation. Ingestion of large amounts may be harmful. Possible mild dermatitis (rash).

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

*Inhalation* : Not an expected route of entry.

*Skin* : May cause mild skin irritation.

*Eyes* : May cause moderate eye irritation. Symptoms include: Irritation, redness and watering.

*Ingestion* : May cause irritation to the mouth, throat 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**

<b><u>Ingredients</u></b>	<b>CAS #</b>	<b>Wt.%</b>
Sodium fluoride	7681-49-4	1.00 - 10.00

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**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 off with soap and plenty of water. If irritation persists, seek prompt medical attention. Wash contaminated clothing before re-use.
- Eye contact** : If in eyes, rinse with water for 15 minutes. Get medical attention.
- Ingestion** : Do NOT induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious person. 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.
- 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** : Hydrofluoric acid; Toxic fumes, gases or vapours may evolve on burning.
- 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. 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** : 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): None reported.

**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.

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- 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.
- Incompatible materials** : Strong acids and oxidizing agents; glass; alkalis; metals.
- 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

### 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

<b>Physical state</b>	: Paste	<b>Appearance</b>	: Various colours.
<b>Odour</b>	: Characteristic odour.	<b>Odour threshold</b>	: N/Av
<b>pH</b>	: 6.5 - 7.5		
<b>Boiling point</b>	: N/Av	<b>Specific gravity</b>	: N/Av
<b>Melting/Freezing point</b>	: N/Av	<b>Coefficient of water/oil distribution</b>	: N/Av
<b>Vapour pressure (mmHg @ 20° C / 68° F)</b>	: N/Av	<b>Solubility in water</b>	: N/Av
<b>Vapour density (Air = 1)</b>	: N/Av	<b>Evaporation rate (n-Butyl acetate = 1)</b>	: N/Av
<b>Volatile organic Compounds (VOC's)</b>	: N/Av	<b>Volatiles (% by weight)</b>	: N/Av
<b>Flash point</b>	: N/Av		
<b>Flash point Method</b>	: N/Av	<b>Auto-ignition temperature</b>	: N/Av
<b>Lower flammable limit (% by vol.)</b>	: N/Av	<b>Upper flammable limit (% by vol.)</b>	: N/Av
<b>Flame Projection Length</b>	: N/Av	<b>Flashback observed</b>	: N/Av
<b>Viscosity</b>	: N/Av		
<b>Absolute pressure of container</b>	: N/Av		

## Section 10: Stability And Reactivity

**Stability and reactivity** : Stable under recommended storage conditions.

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- 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** : *Inhalation:* YES *Skin Absorption:* NO *Skin & Eyes:* YES *Ingestion:* 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>LC<sub>50</sub>(4hr)</u> <u>inh, rat</u>	<u>LD<sub>50</sub></u>	
		<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Sodium fluoride	N/Av	52 mg/kg	175 mg/kg

- 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.  
**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
- Mobility** : No data is available on the product itself.  
**Persistence** : The active ingredient is readily biodegradable.  
**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.

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**SECTION 14: TRANSPORT INFORMATION**

Regulatory Information	UN Number	Shipping Name	Class	Packing Group	Label
TDG	None.	Not regulated.	Not regulated	none	
<b>TDG Additional information</b>	None.				
49CFR/DOT	None.	Not regulated.	Not regulated	none	
<b>49CFR/DOT Additional information</b>	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): None reported.

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. 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 material is not subject to SARA notification requirements, since it does not contain any Toxic Chemical constituents above de minimus concentrations.

**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).

**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

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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  
 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, CCIInfoWeb databases (Chempendium, HSDB and RTECs). (2012)  
 4. US EPA Title III List of Lists (July 2011)  
 5. California Proposition 65 List (16 March 2012)

<p><b><u>Prepared for:</u></b>          A.R. Medicom Inc          1200 55th Avenue          Montreal, QC, Canada, H8T 3J8          Telephone: (514) 636-6262          Direct all enquiries to: A.R. Medicom Inc</p>	
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**DISCLAIMER OF LIABILITY**

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