


Issuing Date: 30 Sept 2020

Revision Date: 30 Sept 2020

ECR# 27238

<i>Section 1. Identification</i>		
Domestic Product Name:	ProDenRx 1.1% NaF NEUTRAL GEL	Part Number(s): 2240MTM
Export Product Name:	ProDenRx 1.1% NaF NEUTRAL GEL	2250MTM
Supplier:	Den-Mat Holdings, LLC 1017 W. Central Ave Lompoc, CA 93436	Phone: 1-805-346-3700 Fax: 805-347-7928
Chemical Use: Anti-Caries preventative. For professional use only. Do not swallow.		

<i>Section 2. Hazard(s) Identification</i>		
Appearance:	Gel of various colors.	
GHS Classification:	Acute toxicity category 3 Eye irritation category 2 Skin irritation category 2	Ratings: Minimal 0 Slight 1 Moderate 2 Severe 3 Extreme 4
Signal Word:	Warning	
Hazard Information:	Hazard Statements: Harmful if swallowed. Causes eye irritation. Causes skin irritation Pictograms:  Harmful Irritant	
Precautionary Information:	Precautionary statements: Keep out of the reach of children. Keep container tightly closed. Wash hands thoroughly after handling.	
Other Hazards:	None	
Unknown Acute Toxicity	No ingredient with unknown toxicity.	

Section 3. Composition and Information for Product Ingredients

Chemical Name	CAS No./ EINECS No.	Synonyms	% W/W
Sodium Fluoride	7681-49-4/231-667-8	N/A	1-2%

Section 4. First Aid Measures

Exposure Scenario	First Aid Measures
Inhalation	Move victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if irritation persists.
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.
Skin Contact	Wash skin with plenty of soap and water. Get medical attention if irritation develops.
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.
Most Important symptoms/effects, acute and delayed:	May cause eye irritation. May be harmful if swallowed.
Indication of immediate medical attention and special treatment needed:	No information available

Section 5. Fire Fighting Measures

Characteristic	Details
Extinguishing Media	Use media appropriate for the surrounding fire.
Unusual Fire/Explosion Hazards	None under normal conditions of use.
Special Protective equipment and precautions for firefighters	Firefighters should wear full emergency equipment and positive pressure self-contained breathing apparatus.
Specific hazards arising from the chemical	None known.
Known or Anticipated Hazardous Products of Combustion	Carbon monoxide, carbon dioxide and toxic fumes.

Section 6. Accidental Release Measures

Measure	Details
Personal precautions, protective equipment and emergency procedures	Avoid contact with eyes, skin and clothing. Use appropriate protective equipment as described in Section 8.
Cleaning/Absorption Measures	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.
Environmental Precautions	Prevent spill from entering waterways.

Section 7. Handling and Storage

Action	Details
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.
Storage	Do not expose to temperature over 40°C (104°F). Keep container tightly closed. Keep out of reach of children. Keep away from strong acids and oxidizing materials.

<i>Section 8. Exposure Controls and Personal Protection</i>	
Action	Details
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 ACGIH TLV TWA 2.5mg/ m ³ OSHA PEL
Engineering Controls	No special ventilation normally required. For bulk handling, use ventilation that is adequate to maintain exposure levels below the occupational exposure limits.
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.
Protective Clothing or Equipment	None needed for normal use. Impervious clothing as needed to avoid contamination of personal clothing for bulk handling.
Eye Protection	Safety glasses recommended for bulk handling. None required for normal use.
Skin Protection	Wear impervious gloves for bulk handling. None required for normal use.

<i>Section 9. Physical and Chemical Properties of Product</i>	
Characteristic	Details
Appearance	Gel of various colors.
pH	6.5-7.5
Boiling point/ Boiling Range	Not available
Melting point/ Freezing Point	Not applicable
Flash Point	Not available
Flammability(solid, gas)	Not available
Flammability & Explosive Limits	LEL: Not available UEL: Not available
Vapor Pressure	Not available
Vapor Density	Not available
Relative Density	Not available
Solubility	Soluble
Odor	Characteristic
Odor Threshold	Not available
Evaporation Rate	Not available
Partition coefficient	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not applicable

<i>Section 10. Stability and Reactivity of Product</i>	
Characteristic	Details
Reactivity	None known.
Chemical Stability	Stable.
Possibility of Hazardous Reactions	None under normal conditions of use.
Conditions to Avoid	Heat
Incompatible Materials	Avoid oxidizing agents and strong acids.
Hazardous Decomposition	May produce carbon monoxide, carbon dioxide and toxic fumes.

<i>Section 11. Health Hazard Information</i>	
Toxicity Category	Details
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
Skin Irritation	Prolonged skin contact may cause irritation.
Eye Irritation	Direct contact causes eye irritation.
Inhalation	No adverse effects expected.
Ingestion	May cause salivation, nausea, vomiting, abdominal pain, headaches, or dizziness.
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) or ACGIH (American Conference of Governmental Industrial Hygienists).
Mutagenicity	No data available.
Chronic Health Effects	Not expected under normal conditions of use. Repeated over exposure to sodium fluoride may cause fluorosis.
Medical Conditions Aggravated by Exposure	Persons with preexisting skin disorders are at increased risk from exposure.

<i>Section 12. Ecological Information</i>	
Characteristic	Details
Ecotoxicity	Ecological data not available for the product itself. Do not allow the product to enter waterways. The data provided are for the ingredients listed below: Sodium Fluoride: 96 hrs. LC50 rainbow trout: 51-108 mg/L
Degradability	No information available
Persistence	No information available
Bioaccumulation	No data available
Mobility in Soil	No data available
Other adverse effects	No information available

<i>Section 13. Disposal of Product</i>	
Measure	Details
Disposal Methods	Dispose in accordance with national and local regulations.
Disposal Container	Dispose in accordance with national and local regulations.
Waste Handling	Dispose in accordance with national and local regulations.

<i>Section 14. Transport Information</i>	
DOT (US)	This is not a DOT controlled material
Proper Shipping Name	Not a regulated material
Hazard Class	N/A
UN Number	N/A
Packing Group	N/A
Air (IATA/ICAO)	This is not a regulated material
Proper Shipping Name	Not a regulated material
Hazard Class	N/A
UN Number	N/A
Packing Group	N/A
IMO/IMDG	This is not a regulated material
Proper Shipping Name	Not a regulated material
Hazard Class	N/A
UN Number	N/A
Packing Group	N/A

<i>Section 15. Regulatory Information</i>	
Category	Details
SARA TITLE III	
Hazard Category for Section 311/312	Acute health.
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 drug 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.

<i>Section 16. Other Information</i>
Risk phrases used in Section 2: Not applicable
Preparation and Release Date: 30 Sept 2020 ECR # 27238
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