

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name 5000 ppm Fluoride Toothpaste for Dry Mouth

Other means of identification

Product Code(s) 1611925

Recommended use of the chemical and restrictions on use

Recommended Use Toothpaste - Solid / Powder

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification Sheffield Pharmaceuticals

Address 170 Broad Street
New London
CT
06320
US

Telephone Phone:860-442-4451
Fax:860-442-0356

E-mail shannon.orenstein@sheffield-pharmaceuticals.com

Emergency telephone number

Company Emergency Phone Number 800-222-1087

2. HAZARDS IDENTIFICATION

Classification

Skin sensitization	Category 1
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Appearance Blue

Physical state Solid containing liquid
Solid

Odor Mint-like

GHS Label elements, including precautionary statements

Warning

Hazard statements

May cause an allergic skin reaction



Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

Skin

IF ON SKIN: Wash with plenty of water and soap
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

May be harmful if swallowed. Causes mild skin irritation.

Unknown acute toxicity 47.6 % of the mixture consists of ingredient(s) of unknown toxicity

- 40 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 46.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Not applicable.

Mixture

Chemical name	CAS No	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
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Glycerin	56-81-5	5	-	-
Poloxamer 407	9003-11-6	1.5	-	-
Sodium fluoride	7681-49-4	1.1	-	-
Mentha piperita oil	8006-90-4	0.6	-	-

4. FIRST AID MEASURES

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms	Itching. Rashes. Hives.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	May cause sensitization in susceptible persons. Treat symptomatically.
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5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by skin contact.
Hazardous Combustion Products	Carbon oxides.
Explosion Data	
Sensitivity to Mechanical Impact	None.
Sensitivity to Static Discharge	None.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name		ACGIH TLV		OSHA PEL		NIOSH IDLH			
Glycerin 56-81-5		TWA: 10 mg/m³ mist		TWA: 15 mg/m³ mist, total particulate TWA: 5 mg/m³ mist, respirable fraction (vacated) TWA: 10 mg/m³ mist, total particulate (vacated) TWA: 5 mg/m³ mist, respirable fraction					
Sodium fluoride 7681-49-4		TWA: 2.5 mg/m³ F		TWA: 2.5 mg/m³ F (vacated) TWA: 2.5 mg/m³		IDLH: 250 mg/m³ F TWA: 2.5 mg/m³ F			
Chemical name		Alberta		British Columbia		Ontario TWAEV		Quebec	
Glycerin 56-81-5		TWA: 10 mg/m³		TWA: 10 mg/m³ TWA: 3 mg/m³				TWA: 10 mg/m³	
Sodium fluoride 7681-49-4		TWA: 2.5 mg/m³		TWA: 2.5 mg/m³		TWA: 2.5 mg/m³		TWA: 2.5 mg/m³	

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls



Engineering controls
Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).
Hand protection Wear suitable gloves.
Skin and body protection Wear suitable protective clothing.
Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Solid containing liquid; Solid
Appearance Blue
Odor Mint-like
Color No information available
Odor Threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks Method</u>
pH	No data available	None known
Melting / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash Point	No data available	None known
Evaporation Rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability limit	No data available	
Lower flammability limit	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water Solubility	Easily soluble	
Solubility(ies)	No data available	None known
Partition coefficient: n-octanol/water	0	
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	78670	

Other Information

Explosive properties No information available
Oxidizing properties No information available
Softening Point No information available
Molecular Weight No information available
VOC Content (%) No information available
Liquid Density No information available
Bulk Density No information available
Particle Size No information available
Particle Size Distribution No information available

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of Hazardous Reactions	None under normal processing.
Hazardous Polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous Decomposition Products	Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available. May cause sensitization by skin contact. (based on components). Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.
Ingestion	May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	Itching. Rashes. Hives.
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Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral)	2,708.70 mg/kg
ATEmix (dermal)	8,511.40 mg/kg

Unknown acute toxicity	47.6 % of the mixture consists of ingredient(s) of unknown toxicity
	40 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
	46.5 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
	47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
	47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
	47.6 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Glycerin	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 2.75 mg/L (Rat) 4 h
Poloxamer 407	= 5700 mg/kg (Rat) = 16 g/kg	-	= 320 mg/m ³ (Rat) 4 h



	(Rat)		
Sodium fluoride	= 52 mg/kg (Rat)	= 175 mg/kg (Rat)	-
Mentha piperita oil	= 2426 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
Serious eye damage/eye irritation	No information available.
Respiratory or skin sensitization	May cause sensitization by skin contact.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Sodium fluoride 7681-49-4	-	Group 3	-	X

Legend

IARC (International Agency for Research on Cancer)

Group 3 - Not Classifiable as to Carcinogenicity in Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerin	.?	96h LC50: 51 - 57 mL/L (Oncorhynchus mykiss)	No data available	.?
Sodium fluoride	96h EC50: = 272 mg/L (Pseudokirchneriella subcapitata) 72h EC50: = 850 mg/L (Desmodesmus subspicatus)	96h LC50: 38 - 68 mg/L (Oncorhynchus mykiss) 96h LC50: = 180 mg/L (Pimephales promelas) 96h LC50: = 830 mg/L (Lepomis macrochirus) 96h LC50: > 530 mg/L (Lepomis macrochirus)	No data available	48h EC50: = 338 mg/L (Daphnia magna) 48h EC50: = 98 mg/L (Daphnia magna)

Persistence and Degradability No information available.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Glycerin	-1.76

Mobility No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

California Waste Codes 311

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical name	California Hazardous Waste
Sodium fluoride 7681-49-4	Toxic

14. TRANSPORT INFORMATION

DOT
Proper Shipping Name
Hazard Class
NOT REGULATED
NON-REGULATED
N/A

TDG Not regulated

MEX Not regulated

ICAO Not regulated

IATA
Proper Shipping Name
Hazard Class
Not regulated
NON REGULATED
N/A

IMDG/IMO
Hazard Class
Not regulated
N/A

RID Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture



International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

CWA (Clean Water Act)

This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium fluoride 7681-49-4	1000 lb			X

CERCLA

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	RQ
Sodium fluoride 7681-49-4	1000 lb		RQ 1000 lb final RQ RQ 454 kg final RQ

US State Regulations



California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

Chemical name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Glycerin 56-81-5	X	X	X	X	
Sodium fluoride 7681-49-4	X	X	X	X	X

16. OTHER INFORMATION

NFPA	Health hazards 2	Flammability 0	Instability 0	Physical and Chemical Properties -
HMIS	Health hazards 2	Flammability 0	Physical hazards 0	Personal Protection X

Prepared By Product Stewardship
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1-800-572-6501

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Revision Note No information available

Disclaimer

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End of Safety Data Sheet