

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name 0.2% Sodium Fluoride Rinse

Other means of identification

Product Code(s) 1611965

Recommended use of the chemical and restrictions on use

Recommended Use Mouthwash, Dental Care - Liquid

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification Sheffield Pharmaceuticals

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New London
CT
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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 Liquid

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**Unknown acute toxicity** 29 % of the mixture consists of ingredient(s) of unknown toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

29 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

29 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

29 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

29 % 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)
Glycerin	56-81-5	24	-	-
Polyethylene-polypropylene glycol	9003-11-6	5	-	-
Supplier Trade Secret	-	0 - 10%	-	-

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.
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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	Dam up. Soak up with inert absorbent material. 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.
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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.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name	ACGIH TLV		OSHA PEL	NIOSH IDLH
Glycerin 56-81-5	TWA: 10 mg/m ³ mist		TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec
Glycerin 56-81-5	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³		TWA: 10 mg/m ³

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

Engineering controls	Showers Eyewash stations Ventilation systems.
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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	Liquid
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	6	
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	1.09	
Water Solubility	Very 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	No data available	None known

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 Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

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

ATEmix (oral) 25,609.80 mg/kg

Unknown acute toxicity 29 % of the mixture consists of ingredient(s) of unknown toxicity

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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
Polyethylene-polypropylene glycol	= 5700 mg/kg (Rat) = 16 g/kg (Rat)	-	= 320 mg/m ³ (Rat) 4 h
Supplier Trade Secret	= 5 g/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.
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	.?

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

14. TRANSPORT INFORMATION

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

TDG Not regulated

MEX Not regulated



<u>ICAO</u>	Not regulated
<u>IATA</u>	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
<u>IMDG/IMO</u>	Not regulated
Hazard Class	N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>ADN</u>	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/NDSL	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/NDSL - 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 does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40



CFR 122.42)

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

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	

16. OTHER INFORMATION

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

Prepared By Product Stewardship
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Revision Note No information available

Disclaimer

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End of Safety Data Sheet