

# SAFETY DATA SHEET

Issuing Date 12-Nov-2020

Revision Date 12-Nov-2020

Revision Number 2

NGHS / English



The supplier identified below generated this SDS using the UL SDS template. UL did not test, certify, or approve the substance described in this SDS, and all information in this SDS was provided by the supplier or was reproduced from publically available regulatory data sources. UL makes no representations or warranties regarding the completeness or accuracy of the information in this SDS and disclaims all liability in connection with the use of this information or the substance described in this SDS. The layout, appearance and format of this SDS is ©2014 UL LLC. All rights reserved.

## 1. IDENTIFICATION

### Product identifier

**Product Name** 5000 ppm Fluoride Enamel Protect Toothpaste

### Other means of identification

**Product Code(s)** 1611934

### 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
--------------------	------------



**Appearance** White to off-white

**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** 50.5 % of the mixture consists of ingredient(s) of unknown toxicity

38.2 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

49.4 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

50.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

50.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

50.5 % 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)
---------------	--------	----------	---	---

Sodium fluoride	7681-49-4	1.1	-	-
Titanium dioxide	13463-67-7	0.5	-	-
Sodium lauryl sulfate	151-21-3	0.5	-	-
Supplier Trade Secret	-	0 - 10%	-	-
Supplier Trade Secret	-	0 - 10%	-	-

#### 4. FIRST AID MEASURES

##### Description of first aid measures

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

##### Most important symptoms and effects, both acute and delayed

<b>Symptoms</b>	Itching. Rashes. Hives.
-----------------	-------------------------

##### Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	May cause sensitization in susceptible persons. Treat symptomatically.
---------------------------	--

#### 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Hazardous Combustion Products</b>	Carbon oxides.
<b>Explosion Data</b>	
<b>Sensitivity to Mechanical Impact</b>	None.
<b>Sensitivity to Static Discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	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	
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	
Titanium dioxide 13463-67-7	TWA: 10 mg/m³	TWA: 15 mg/m³ total dust (vacated) TWA: 10 mg/m³ total dust	IDLH: 5000 mg/m³	
Chemical name	Alberta	British Columbia	Ontario TWAEV	Quebec
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
Titanium dioxide 13463-67-7	TWA: 10 mg/m³	TWA: 10 mg/m³ TWA: 3 mg/m³	TWA: 10 mg/m³	TWA: 10 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**

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

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	Solid containing liquid; Solid
<b>Appearance</b>	White to off-white
<b>Odor</b>	Mint-like
<b>Color</b>	No information available
<b>Odor Threshold</b>	No data available

<b><u>Property</u></b>	<b><u>Values</u></b>	<b><u>Remarks Method</u></b>
<b>pH</b>	No data available	None known
<b>Melting / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flash Point</b>	No data available	None known
<b>Evaporation Rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability limit</b>	No data available	
<b>Lower flammability limit</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water Solubility</b>	Easily soluble	
<b>Solubility(ies)</b>	No data available	None known
<b>Partition coefficient: n-octanol/water</b>	0	
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	122083	

<b><u>Other Information</u></b>	
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Softening Point</b>	No information available
<b>Molecular Weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk Density</b>	No information available
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available

**10. STABILITY AND REACTIVITY**

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

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	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.
<b>Ingestion</b>	May be harmful if swallowed.

### Symptoms related to the physical, chemical and toxicological characteristics

<b>Symptoms</b>	Itching. Rashes. Hives.
-----------------	-------------------------

### Numerical measures of toxicity

#### Acute toxicity

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

<b>ATEmix (oral)</b>	2,656.70 mg/kg
<b>ATEmix (dermal)</b>	8,050.00 mg/kg

**Unknown acute toxicity** 50.5 % of the mixture consists of ingredient(s) of unknown toxicity  
 38.2 % of the mixture consists of ingredient(s) of unknown acute oral toxicity  
 49.4 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity  
 50.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)  
 50.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)  
 50.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

#### Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium fluoride	= 52 mg/kg ( Rat )	= 175 mg/kg ( Rat )	-
Titanium dioxide	> 10000 mg/kg ( Rat )	-	-
Sodium lauryl sulfate	= 1288 mg/kg ( Rat )	= 200 mg/kg ( Rabbit )	> 3900 mg/m <sup>3</sup> ( Rat ) 1 h
Supplier Trade Secret	= 5 g/kg ( Rat )	-	-
Supplier Trade Secret	= 2426 mg/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	Classification based on data available for ingredients. This product contains titanium dioxide in a non-respirable form. Inhalation of titanium dioxide is unlikely to occur from exposure to this product.

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
Titanium dioxide 13463-67-7	-	Group 2B	-	X

**Legend**

**IARC (International Agency for Research on Cancer)**

Group 2B - Possibly Carcinogenic to Humans

Group 3 - Not Classifiable as to Carcinogenicity in Humans

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

X - Present

<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	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
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)
Sodium lauryl sulfate	96h EC50: 3.59 - 15.6 mg/L (Pseudokirchneriella subcapitata) 96h EC50: 30 - 100 mg/L	96h LC50: 10.2 - 22.5 mg/L (Pimephales promelas) 96h LC50: 10.8 - 16.6 mg/L (Poecilia reticulata) 96h LC50:	EC50 = 0.46 mg/L 30 min EC50 = 0.72 mg/L 15 min EC50 = 1.19 mg/L 5 min	48h EC50: = 1.8 mg/L (Daphnia magna)

	(Desmodesmus subspicatus) 96h EC50: = 117 mg/L (Pseudokirchneriella subcapitata) 72h EC50: = 53 mg/L (Desmodesmus subspicatus)	13.5 - 18.3 mg/L (Poecilia reticulata) 96h LC50: 15 - 18.9 mg/L (Pimephales promelas) 96h LC50: 22.1 - 22.8 mg/L (Pimephales promelas) 96h LC50: 4.06 - 5.75 mg/L (Lepomis macrochirus) 96h LC50: 4.2 - 4.8 mg/L (Lepomis macrochirus) 96h LC50: 4.3 - 8.5 mg/L (Oncorhynchus mykiss) 96h LC50: 5.8 - 7.5 mg/L (Pimephales promelas) 96h LC50: 6.2 - 9.6 mg/L (Pimephales promelas) 96h LC50: 8 - 12.5 mg/L (Pimephales promelas) 96h LC50: 9.9 - 20.1 mg/L (Brachydanio rerio) 96h LC50: = 1.31 mg/L (Cyprinus carpio) 96h LC50: = 4.2 mg/L (Oncorhynchus mykiss) 96h LC50: = 4.5 mg/L (Lepomis macrochirus) 96h LC50: = 4.62 mg/L (Oncorhynchus mykiss) 96h LC50: = 7.97 mg/L (Brachydanio rerio)		
--	---	---	--	--

**Persistence and Degradability** No information available.

**Bioaccumulation**

**Component Information**

Chemical name	Partition coefficient
Sodium lauryl sulfate	1.6

**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 NOT REGULATED  
Hazard Class NON-REGULATED  
N/A

**TDG** Not regulated

**MEX** Not regulated

**ICAO** Not regulated

**IATA**  
Proper Shipping Name Not regulated  
Hazard Class 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/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 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 contains the following Proposition 65 chemicals.

Chemical name	California Proposition 65
Titanium dioxide - 13463-67-7	Carcinogen

### 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
Sodium fluoride 7681-49-4	X	X	X	X	X
Titanium dioxide 13463-67-7	X	X	X		

## 16. OTHER INFORMATION



---

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

**Prepared By** Product Stewardship  
23 British American Blvd.  
Latham, NY 12110  
1-800-572-6501

**Issuing Date** 12-Nov-2020

**Revision Date** 12-Nov-2020

**Revision Note** No information available

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**