SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier	
Product Name	5000 ppm Fluoride Fruit TP
Other means of identification	
Product Code(s)	1565861
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

Not classified.

The product contains no substances which at their given concentration, are considered to be hazardous to health



Appearance Pink

Physical state Solid containing liquid Solid

Odor Fruity

GHS Label elements, including precautionary statements

Hazard statements

Not classified.

Other information

May be harmful if swallowed. Causes mild skin irritation.

Unknown acute toxicity

9.72 % of the mixture consists of ingredient(s) of unknown toxicity

1.12 % of the mixture consists of ingredient(s) of unknown acute oral toxicity 8.62 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

9.72 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

9.72 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

9.72 % 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)
Silica, amorphous, precipitated and gel	112926-00-8	15.5	-	-
Sodium fluoride	7681-49-4	1.1	-	-
Supplier Trade Secret	-	0 - 10%	-	-
Sodium lauryl sulfate	151-21-3	0.5	-	-

4. FIRST AID MEASURES

Description of first aid measures

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 skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

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	No information available.
Hazardous Combustion Products	Carbon oxides.
Explosion Data Sensitivity to Mechanical Impac Sensitivity to Static Discharge	t None. 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 eyes.		

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.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place.



8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name		ACGIH TLV		OSHA PEL		1	NIOSH IDLH
Silica, amorphous, precipit	ated	-		(vacated) TWA: 6 mg/m ³			
and gel 112926-00-8							
Sodium fluoride		TWA: 2.5 mg	ŋ/m³ F	TWA:	2.5 mg/m ³ F	IDL	H: 250 mg/m³ F
7681-49-4			y ,	(vacated)	TWA: 2.5 mg/m ³		A: 2.5 mg/m ³ F
Supplier Trade Secret		TWA: 10 m	g/m³		mg/m ³ total dust	IDL	H: 5000 mg/m ³
				(vacated) TV	VA: 10 mg/m ³ total		
					dust		
Chemical name		Alberta	British C	Columbia	Ontario TWAE	V	Quebec
Silica, amorphous,				l mg/m³			TWA: 6 mg/m ³
precipitated and gel 112926-00-8			TWA: 1.	5 mg/m ³			
Sodium fluoride 7681-49-4	T١	WA: 2.5 mg/m ³	TWA: 2.	5 mg/m³	TWA: 2.5 mg/n	1 ³	TWA: 2.5 mg/m ³
Supplier Trade Secret	Т			0 mg/m³ 8 mg/m³	TWA: 10 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).

Appropriate engineering controls

Engineering controls	Showers
	Eyewash stations
	Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.

Skin and body protection No special protective equipment required.

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	Pink		
Odor	Fruity		
Color	No information available		
Odor Threshold	Not applicable		
Property_	Values_	Remarks Method	
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/wa	ater0	
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.
Ingestion	May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

No information available.

Numerical measures of toxicity

Acute Toxicity

The following values are calculated based on chapter 3.1 of the GHS documentATEmix (oral)4,624.30 mg/kg

Unknown acute toxicity 9.72 % of the mixture consists of ingredient(s) of unknown toxicity

1.12 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

8.62 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

9.72 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

9.72 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

9.72 % 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)	-	
Supplier Trade Secret	> 10000 mg/kg (Rat)	-	-	
Sodium lauryl sulfate	= 1288 mg/kg (Rat)	= 200 mg/kg (Rabbit)	> 3900 mg/m3 (Rat) 1 h	

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	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	Classification based on data available for ingredients.

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

Chemical name	ACGIH	IARC	NTP	OSHA
Silica, amorphous,	-	Group 3	-	-
precipitated and gel				
112926-00-8				
Sodium fluoride	-	Group 3	-	Х
7681-49-4				
Supplier Trade Secret	-	Group 2B	-	Х

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

Reproductive toxicity

No information available. No information available.

STOT - single exposure



STOT - repeated exposure

No information available.

No information available.

Aspiration hazard

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

Chemical name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Sodium fluoride	72h EC50: = 850 mg/L	96h LC50: 38 - 68 mg/L	-	48h EC50: = 98 mg/L
	(Desmodesmus	(Oncorhynchus mykiss)		(Daphnia magna) 48h
	subspicatus) 96h EC50:	96h LC50: = 180 mg/L		EC50: = 338 mg/L
	= 272 mg/L	(Pimephales promelas)		(Daphnia magna)
	(Pseudokirchneriella	96h LC50: = 830 mg/L		
	subcapitata)	(Lepomis macrochirus)		
		96h LC50: > 530 mg/L		
	00h EQE0: 20, 400	(Lepomis macrochirus)		
Sodium lauryl sulfate	96h EC50: 30 - 100	96h LC50: 9.9 - 20.1	EC50 = 0.46 mg/L 30 min EC50 = 0.72 mg/L 15 min	48h EC50: = 1.8 mg/L
	mg/L (Desmodesmus subspicatus) 96h EC50:	96h LC50: 10.2 - 22.5	EC50 = 0.72 mg/L 15 min EC50 = 1.19 mg/L 5 min	(Daphnia magna)
	= 117 mg/L	mg/L (Pimephales	EC50 = 1.19 mg/E 5 mm	
	(Pseudokirchneriella	promelas) 96h LC50: 15		
	subcapitata) 72h EC50: =	, ,		
	53 mg/L (Desmodesmus	promelas) 96h LC50:		
	subspicatus) 96h EC50:	4.2 - 4.8 mg/L (Lepomis		
	3.59 - 15.6 mg/L	macrochirus) 96h LC50:		
	(Pseudokirchneriella	= 4.5 mg/L (Lepomis		
	subcapitata)	macrochirus) 96h LC50:		
		= 4.2 mg/L		
		(Oncorhynchus mykiss)		
		96h LC50: 22.1 - 22.8		
		mg/L (Pimephales		
		promelas) 96h LC50:		
		4.3 - 8.5 mg/L		
		(Oncorhynchus mykiss)		
		96h LC50: 13.5 - 18.3 mg/L (Poecilia reticulata)		
		96h LC50: 6.2 - 9.6		
		mg/L (Pimephales		
		promelas) 96h LC50: =		
		1.31 mg/L (Cyprinus		
		carpio) 96h LC50: 10.8 -		
		16.6 mg/L (Poecilia		
		reticulata) 96h LC50: 8 -		
		12.5 mg/L (Pimephales		
		promelas) 96h LC50:		
		5.8 - 7.5 mg/L		
		(Pimephales promelas)		
		96h LC50: = 4.62 mg/L		
		(Oncorhynchus mykiss)		
		96h LC50: 4.06 - 5.75		
		mg/L (Lepomis		
		macrochirus) 96h LC50: = 7.97 mg/L		
		(Brachydanio rerio)		
L				

Persistence and Degradability No inf

No information available.



Bioaccumulation

Component Information

	name	Log Pow			
Sodium lauryl sulfate		1.6			
lobility	No information available.				
Other adverse effects	No information available.				
13. DISPOSAL CONSIDERATIONS					
Vaste treatment methods_					
Vaste from residues/unused roducts	Dispose of in accordance environmental legislation.	rdance with local regulations. Dispose of waste in accordance with slation.			
contaminated packaging	Do not reuse empty contai	containers.			

California Waste Codes	311
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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	Toxic	
7681-49-4		

14. TRANSPORT INFORMATION

NOT REGULATED NON-REGULATED N/A
Not regulated
Not regulated
Not regulated
Not regulated NON REGULATED N/A
Not regulated N/A
Not regulated
Not regulated
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			Х

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

<u>California Proposition 65</u> 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
Silica, amorphous, precipitated and gel 112926-00-8	Х	Х	Х		
Sodium fluoride 7681-49-4	Х	Х	Х	Х	Х
Supplier Trade Secret	Х	Х	Х		

16. OTHER INFORMATION				
NFPA	Health hazards 1	Flammability 0	Instability 0	Physical and Chemical Properties -
<u>HMIS</u>	Health hazards 1	Flammability 0	Physical hazards 0	Personal Protection X
Prepared By				
Issuing Date	19-Mar-2020			
Revision Date	16-Mar-2020			
Revision Note	No information available			

Disclaimer

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End of Safety Data Sheet