

Section 1 – Identification

Product Name: Ionite Acidulated Phosphate Fluoride Gel (Various Flavors) **Manufacturer:** Dharma Research, Inc.
 5220 N.W. 72nd Avenue, Unit #15
 Miami, FL 33166

Active Ingredient: Sodium Fluoride **Information Contacts:** (305) 482-9669
Toll Free: (877) 833-3725
Emergency Phone Numbers: US & Canada: (877) 833-3725

Family: Fluoride Treatment
Product Use: Professional Dental Preventive Care
Product #: Various

Section 2 – Hazards Identification

EMERGENCY OVERVIEW

This information is based on findings from related or similar materials.

- Will cause eye irritation.
- May cause skin irritation.
- Prolong exposure may cause respiratory system irritation.
- Ingestion of large amounts may cause nausea, vomiting, headaches, or dizziness.
- Please read entire MSDS for additional information.



Potential Health Effects, Signs and Symptoms of Exposure:

Primary Route of Entry Inhalation, skin, and ingestion.

Eye Vapors are irritating to the eyes. Splashes may cause redness of the eye.

Skin Repeated/prolonged contact may cause mild irritation of the skin. Symptoms include redness, burning, or itching.

Ingestion Swallowing small amounts during normal handling is not likely to cause harmful effects; swallowing large amounts may be harmful. Symptoms include irritation of the throat, nausea, dizziness, and upset stomach.

Inhalation If fine small particles are inhaled, irritation of the throat with a feeling of tightness in the chest may occur.

NOTE: Refer to Section 11, Toxicological Information for Details

Section 3 – Composition/Information on Ingredients

Chemical Identity	CAS Numbers	EINECS#	INCI Name	Exposure OSHA	Limits ACGIH	Carcinogen	%
				TWA/STEL	TWA/STEL		
Phosphoric Acid	7664-38-2	231-633-2	Phosphoric Acid	TWA = 1 mg/ m ³	TWA = 1 mg/ m ³ STEL = 3 mg/ m ³	Not listed	1-5
Sodium Fluoride	7681-49-4	231-667-8	Sodium Fluoride	TWA = 3ppm / 6ppm	2.5 mg / m ³	Not Listed	1-3

N/E – None Established N/DA – No Data Available
 N/R – Not Reviewed N/A – Not Applicable

(items in parenthesis relate to 1999/45/EC)

Phosphoric Acid: Danger Symbol – GHS05 (C) Hazard Statement – H314 (R34) Precautionary Statement – P102 (S1/2), P305+334 (S26), P309+314 (S45)

Sodium Fluoride: Danger Symbol – GHS06 (T), GHS07 (Xi) Hazard Statement – H301 (R25), EUH032 (R32), H315 (R38), H319 (R36) Precautionary Statement – P102 (S2), P260 (S23), P280 (S36/37/39), P309+314 (S45)

See Section 16 for Hazard and Precautionary Statement Key.

Section 4 – First Aid Measures

First Aid for Eye Flush with water for 15 minutes, including under eyelids. Get medical help if discomfort persists.

First Aid for Skin Wash thoroughly with soap and water. Remove contaminated clothing. Get medical help if discomfort persists.

First Aid for Ingestion If greater than normal dose is swallowed, do not induce vomiting. Drink large quantity of water or milk. Seek medical attention.

First Aid for Inhalation Move to fresh air. If having breathing difficulty, give oxygen. Seek medical attention if discomfort persists.

Section 5 – Fire Fighting Measures

Flash Point (°F/°C)	Flammable Limit (vol%)	Auto-ignition Temperature (vol%)
N/A	N/A	N/A

Method:

Extinguishing Media: Carbon dioxide, dry chemical foam

Fire Fighting Instructions: During a fire, irritating or highly toxic gases may be generated by thermal decomposition. If potential for exposure, wear complete personal protective equipment including self contained breathing apparatus, with full face operated in pressure demand.

Unusual Hazards: Evacuate all personnel.

Section 6 – Accidental Release Measures

Spill or Release Procedures Minor spills – Clean up immediately, avoid contact with skin and eyes. Mop / wipe area and clean with soapy water

Major spills – Clear area of personnel. Restrict access to area. Avoid contact with skin and eyes, and dilute area with soapy water. Collect contaminated water and dispose of properly.

See section 8 & section 12.

Section 7 – Handling and Storage

Handling Limit all unnecessary personal contact. Avoid breathing vapors. Wear appropriate PPE.

Storage Store in a cool, well ventilated area away from heat, sparks and flame. Keep containers closed when not in use. Keep in original container provided by manufacturer.

Explosion Hazard None.

Section 8 – Exposure Controls / Personal Protection

Engineering Controls General exhaust is adequate under normal operating conditions.

Personal Protective Equipment

General To identify additional Personal Protective Equipment (PPE) requirements, it is recommended that a hazard assessment in accordance with the OSHA PPE Standard (29CFR1910.132), or European Standard EN166 be conducted before using this product.

Eye/ Face Protection Safety glasses / goggles or splash shields are required when handling. Ensure eye bath is on hand.

Skin Protection Use impermeable clothing to prevent ANY contact with this product, such as gloves, apron, boots, or whole body suit.

Respiratory Protection In case of insufficient ventilation, wear suitable respiratory equipment.

Section 9 – Physical and Chemical Properties

Appearance Gel	Odor & Odor Threshold Odor of Stated Flavor	pH N/A	Specific Gravity (H2O = 1): N/A	Viscosity N/A	% Volatile N/A		
Boiling Point/ Freezing Point	Decomposition Temperature	Octanol/Water Partitioning Coefficient Log Po/w	Vapor Pressure:	Vapor Density	Evaporation Rate	Ignition	Solubility In Water (20°C)
N/A	N/DA	N/DA	N/A	N/A	N/A	N/A	N/A
Flash Point (°F/°C)		Flammable Limit (vol%)		Auto-ignition Temperature (vol%)			
N/A		N/A		N/A			

Section 10 – Stability and Reactivity

Stability: Stable	Incompatibility (Materials to Avoid): Strong Acids
Hazardous Decomposition Products: Toxic Fumes (HF)	Hazardous Polymerization: Will not occur
Conditions to Avoid: Heat and incompatible materials	

Section 11 – Toxicological Information

Acute Oral Toxicity N/DA	Acute Dermal Toxicity N/DA	Acute Inhalation Toxicity N/DA	Irritation – skin N/DA	Irritation – Eye N/DA
Sensitization N/DA		Mutagenicity N/DA	Sub-chronic Toxicity N/DA	

Section 12 – Ecological Information
Ecotoxicological Information

Acute Toxicity to Fish N/DA	Acute Toxicity to Invertebrates N/DA	Acute Toxicity to Algae N/DA	Bioconcentration N/DA	Toxicity to Sewage Bacteria N/DA
---------------------------------------	--	--	---------------------------------	--

Chemical Fate Information

Biodegradability	Biodegradable. This material is not expected to significantly bio-accumulate.
Chemical Oxygen Demand	N/DA

Section 13 – Disposal Considerations

Dispose of in compliance with governmental regulation (state and federal).

Dispose of container and unused contents in accordance with federal, state and local requirements. For EU Member States, please refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

Section 14 – Transport Information

DOT (49 CFR 172)	
Proper Shipping Name:	Non-regulated material
Identification Number:	N/A
Marine Pollutant:	No
Special Provisions:	N/A
Emergency Response Guidebook (ERG) #:	N/A
IATA (DGR):	
Proper Shipping Name:	Non-regulated material
Class or Division:	N/A
UN or ID Number:	N/A
Packaging Instructions:	N/A
Emergency Response Guidance (ICAO)#:	N/A
IMO (IMDG):	
Proper Shipping Name:	Non-regulated material
Class or Division:	N/A
UN or ID Number:	N/A
Special Provisions & Stowage/Segregation:	N/A
Emergency Schedule (EmS)#:	N/A
Other Information:	N/A

Section 15 – Regulatory Information

US Federal Regulations

Clean Air Act: HAP/ODS	This product contains the following HAP’s or ODS: <ul style="list-style-type: none"> • NONE
Clean Water Act: Priority Pollutant	This product contains the following chemicals listed under the U. S. Clean Water Act Priority Pollutant and Hazardous Substance List: <ul style="list-style-type: none"> • None
FDA: Food Packaging Status	This product has not been cleared by the FDA for use in food packaging and / or other applications as an indirect food-packaging additive.
Occupational Safety and Health Act	This product is considered to be hazardous under the OSHA Hazard Communication Standard. It’s hazards are: <ul style="list-style-type: none"> • Phosphoric Acid CAS # 7664-38-2 (Corrosive)
RCRA	This product contains the following chemicals considered to be hazardous waste under RCRA (40 CFR 261). <ul style="list-style-type: none"> • None
SARA Title III: Section 302 (RQ)	This product contains no chemicals regulated under Section 302 as extremely hazardous substances.
SARA Title III: Section 302 (TPQ)	This product contains chemicals regulated under Section 304 as extremely hazardous chemicals for emergency release notification (“CERCLA” List): <ul style="list-style-type: none"> • Sodium Fluoride – CAS #7681-49-4 1000 # RQ
SARA Title III: Section 311-312:	This product is considered to be hazardous under the OSHA Hazard Communication Standard and is regulated under Section 311-312 (40 CFR 370). It’s hazards are: <ul style="list-style-type: none"> • Sodium Fluoride – CAS# 7681-49-4 (Corrosive) • Phosphoric Acid CAS #7664-38-2 (Corrosive)
SARA Title III: Section 313:	This product contains the following chemicals which are subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372: <ul style="list-style-type: none"> • None

Safety Data Sheet

“IONITE” APF FLUORIDE GEL

TSCA Section 8(b): Inventory:	This product does contain chemicals listed on the TSCA inventory or otherwise complies with TSCA pre-manufacture notification requirements. <ul style="list-style-type: none"> Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS #7664-38-2 None of the chemicals in this material have a SNUR under TSCA.
TSCA Significant New Use Rule:	


State Regulations

CA Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4
California No Significant Risk Rule:	None
MA Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS # 7664-38-2
NJ Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS # 7664-38-2
PA Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS # 7664-38-2
FL Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4
MN Right-to-Know Law:	Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS # 7664-38-2

International Regulations

CDSL: Canadian Inventory (on Canadian Transitional List)	Sodium Fluoride – CAS# 7681-49-4 Phosphoric Acid CAS # 7664-38-2
--	---

Labeling according to EC directives – 1272/2008 {CLP} AND 1999/45/EC (items in parenthesis relate to 1999/45/EC)

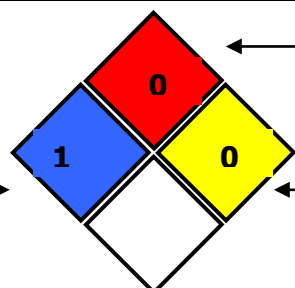
European Community: 	For Ionite APF Fluoride Gel (finished product): <ul style="list-style-type: none"> DANGER SYMBOLS: GHS07 (Xi) – Warning / Irritant HAZARD STATEMENT: H316 (N/A), Causes mild skin irritation. H319 (R36), Causes serious eye irritation. H335 (R37), May cause respiratory irritation. H303 (N/A), May be harmful if swallowed. PRECAUTIONARY STATEMENT: P102 (S2), Keep out of reach of children. P210 (S15), Keep away from heat/sparks/open flames/hot surfaces. P261 (S24), Avoid breathing dust/fume/gas mist/vapor sprays. P280 (S36/37/39), Wear protective gloves/clothing/eye protection/face protection. P309+314 (S45), If exposed or you feel unwell, get medical advice/attention.
--	---

Section 16 – Other Information

EU Classes and Risk / Safety Phrases for Referenced Ingredients (See Section 2):

(items in parenthesis relate to 1999/45/EC) Danger Symbols: GHS06 (T) – Toxic. GHS07 (Xi) – Warning / Irritants. GHS05 (C) - Corrosive Hazard Statement: H301 (R25) , Toxic if swallowed. H314 (R34) , Causes severe skin burns and eye damage. H315 (R38) , Causes skin irritation. H316 (N/A) Causes mild skin irritation. H319 (R36) , Causes serious eye irritation. H335 (R37) , May cause respiratory irritation. H336 (R67) , May cause drowsiness or dizziness. EUH032 (R32) , Contact with acid liberates very toxic gas. H303 (N/A) , May be harmful if swallowed. Precautionary Statement: P102 (S1 or S2) , Keep out of reach of children. P210 (S15) , Keep away from heat/sparks/open flames/hot surfaces. P260 (S23) , Do not breathe dust/fume/gas/mist/vapors/spray. P261 (S24) , Avoid breathing dust/fume/gas mist/vapor sprays. P280 (S36/37/39) , Wear protective gloves/clothing/eye protection/face protection. P305+334 (S26) , In case of contact with eyes, rinse immediately with water. P309+314 (S45) , If exposed or you feel unwell, get medical advice/attention. P404 (S7) , Store in a closed container. P403+235 (S3/9) , Store in a well ventilated place. Keep cool.
--

Hazard Rating System (Pictograms)

<p>NFPA:</p> <div style="display: flex; align-items: center; justify-content: center;"> <div style="text-align: center; margin-right: 20px;">  <p>Health →</p> </div> <div style="text-align: center;"> <p>← Flammability</p> <p>← Reactivity</p> </div> </div>	<p>HMIS:</p> <div style="border: 1px solid black; padding: 5px;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; width: 30px;">1</td> <td style="background-color: #0070C0; color: white; padding: 5px;">Health</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="background-color: #FF0000; color: white; padding: 5px;">Flammability</td> </tr> <tr> <td style="text-align: center;">0</td> <td style="background-color: #FFFF00; color: black; padding: 5px;">Reactivity</td> </tr> <tr> <td colspan="2" style="height: 30px;"></td> </tr> </table> </div>	1	Health	0	Flammability	0	Reactivity		
1	Health								
0	Flammability								
0	Reactivity								

Prepared By:	Ricardo Carles
Revision History:	6/16/2015 Revision B

The information presented herein was obtained from sources considered to be reliable. However, this information is provided without any warranty, expressed or implied, regarding its correctness or suitability for consumers intended use and/or application. For this and other reasons, we assume no responsibility and expressly disclaim liability for loss, damage or expense arising out of any way connected with the handling, storage, use or disposal of the product. This SDS was prepared expressly for this product. Use the materials only as directed. If the product is used as a component of another product, the information contained within the SDS may not be applicable.

Dharma components are provided on an as is basis without warranties of any kind either expressed or implied. Dharma does not warrant the use or the results of use of the materials sold on an as is basis since they are intended for remanufacturing or repackaging. It is the sole responsibility of the user to examine and determine appropriate application and regulatory requirements associated with said Dharma components.