



Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Document Number: SDS 089.001
Date Revised: 11/30/2015

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	Acidulated Phosphate Fluoride Gel
Product Form:	Mixture
Part/Item Number:	009-3900; 009-4000; 009-4100; 009-4200; 009-4300; 009-4500; 009-4600

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	Topical Fluoride Treatment
Restrictions on Use:	For Professional Use Only. Do not use on persons hypersensitive to fluoride or other formula ingredients.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	Dental Technologies, Inc.
Manufacturer/Supplier Address:	6901 N. Hamlin Avenue Lincolnwood, IL 60712
Manufacturer/Supplier Telephone Number:	800-835-0885 or 847-677-5500 (Product Information)
Email address:	info@dentaltech.com

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	Chemtrec
	800-424-9300 (USA)
	001-703-527-3887 (Outside USA)

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Skin Irritant Category 2 Eye Irritant Category 2	Not Hazardous	No Physical Hazards

EU Classification (1999/45/EC as amended): Not classified

Refer to Section 16 for the full text of the EU Classifications and R Phrases.

2.2 Label Elements:

Hazard pictograms (GHS-US)



GHS07

Signal Word: Warning

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation H319 Causes serious eye irritation	P264 Wash exposed skin thoroughly after handling. P280 Wear protective gloves, and eye protection. P302 + P352 IF ON SKIN: Wash with plenty of water. P332 + P313 If skin irritation occurs: Get medical attention. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 If eye irritation persists: Get medical attention P362 + P362 Take off contaminated clothing and wash it before reuse. P501 Dispose of contents and container in accordance with local and national regulations.

2.3 Other Hazards: None known.**2.4 Unknown acute toxicity (GHS-US):** No data available.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances: Not Applicable**3.2 Mixture**

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Sodium Fluoride	7681-49-4	231-667-8	T, Xi, R25, R36/38, R32 Acute Tox Cat 3 (H301), Skin Irrit Cat 2 (H315), Eye Irrit Cat 2 (H319), EUH032	1-3%
Phosphoric Acid	7664-38-2	231-663-2	C, R34 Skin Corr. Cat 1B, (H314)	<2%
Hydrofluoric Acid	7664-39-3	231-634-8	C, T R26/27/28, R35 Acute Tox 2 (H300), Acute Tox 1 (H310), Acute Tox 2 (H330), Skin Corr 1A (H314)	<2%

The exact concentration is being withheld as a trade secret.**Refer to Section 16 for the full text of the GHS and EU Classifications.**

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:

Eye	Immediately flush victim's eyes with large quantities of water for several minutes, holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water. If irritation develops, get medical attention. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. Keep at rest in a position comfortable for breathing. If breathing is difficult, provide artificial respiration.
Ingestion	Do not induce vomiting. If conscious, rinse mouth with a small amount of water and give one glass of water to dilute. Never give anything by mouth to an unconscious or convulsing person. Get medical

	attention if you feel unwell.
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4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
 May cause eye and skin irritation. May be harmful if swallowed. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
 Immediate medical attention should not be required except in cases of high quantities of ingestion.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.





5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media: Use appropriate media for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture:
 Decomposition may release oxides of carbon, phosphorous, fluorine, and sodium.



5.3 Advice for Fire-Fighters:

Fire Fighting Procedures:	Use water to cool exposed containers and structures.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from firefighting to enter drains or water courses.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	HANDS	RESPIRATORY	THERMAL
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
 Remove all ignition sources such as open flames, spark producing equipment, pilot lights, etc. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	HANDS	RESPIRATORY	SKIN
			

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local, state, and national authorities. Avoid contact with skin, eyes or clothing. Wear appropriate protective clothing as described in Section 8.

6.3 Methods and Material for Containment and Cleaning up:

Clean up with absorbent material and remove residue with alcohol damp wipe. Rinse spill area with water. Use non-sparking tools and equipment.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handling:

Avoid contact with the eyes. Avoid prolonged contact with skin. Wear protective clothing and equipment as described in Section 8. Wash thoroughly with soap and water after handling. Keep containers closed when not in use.

Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area away from heat, direct sunlight and all sources of ignition. Store away from incompatible materials. Keep container closed to prevent contamination.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters: No additional information available.

Occupational Exposure Limits:

Sodium Fluoride (As Fluoride)	United States	2.5 mg/m ³ ACGIH TLV TWA 2.5 mg/m ³ OSHA PEL TWA
	Germany	1 mg/m ³ (Inhalable, skin) DFG MAK
	United Kingdom	None established
	European Union	None established
Phosphoric Acid	United States	1 mg/m ³ TWA, 3 mg/m ³ STEL ACGIH TLV 1 mg/m ³ TWA OSHA PEL
	Germany	2 mg/m ³ DFG MAK (Inhalable fraction)
	United Kingdom	1 mg/m ³ TWA UK WEL, 2 mg/m ³ STEL

	European Union	1 mg/m ³ TWA, 2 mg/m ³ / STEL
Hydrofluoric Acid (As Fluoride)	United States	0.5 ppm TWA, 2 ppm STEL ACGIH TLV 3 ppm TWA OSHA PEL
	Germany	1 ppm DFG MAK
	United Kingdom	1.8 ppm TWA, 3 ppm STEL UK WEL
	European Union	1.8 ppm TWA, 3 ppm STEL

8.2 Exposure Controls:

Appropriate Engineering Controls: None required under normal product handling conditions.

Individual Protection Measures (PPE)



Specific Eye/face Protection: Chemical safety goggles should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear impervious gloves such as natural rubber or neoprene if needed to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. If exposure limits are exceeded an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment

EYES/FACE	HANDS	RESPIRATORY	SKIN
			

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Homogeneous Opaque Gel	Relative density:	1.01 to 1.06g/cc @25°C/77°F
Color:	Various colors	Melting Point:	Not determined
Odor:	Various flavors	Boiling Point:	Not determined
Odor threshold:	Not determined	Solubility in Water:	Partially Soluble
Viscosity:	7,000 – 20,000 cps	pH:	3.00-4.00
Other Data:	Not applicable – Product not regulated for VOC Content at State of Federal Level.		

9.2 Other Information: None available.

10. STABILITY AND REACTIVITY

10.1 Reactivity: Stable at ambient temperature and under normal conditions of use.

10.2 Chemical Stability: Stable at standard temperature and pressure.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Keep away from heat, sparks, incompatible materials, flames and other sources of ignition.

10.5 Incompatible materials: High temperatures, strong oxidizing agents. Keep away from sunlight and open flames.

10.6 Hazardous Decomposition Products: Decomposition may produce oxides of carbon, fluoride, and sodium.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Contact with eyes may cause moderate to severe irritation with redness and tearing.

Skin: May cause irritation. Prolonged exposure may cause irritation or dermatitis.

Ingestion: Swallowing small amounts may cause irritation of the mouth and throat, salivation, nausea, vomiting. Large amounts may cause abdominal pain, weakness, tremor, spasm, or convulsions. Death may occur from respiratory paralysis.

Inhalation: No adverse effects are expected under normal use conditions.

Chronic Health Effects: Prolonged overexposure may cause drying of the skin and irritation. Prolonged over exposure to sodium fluorides may cause fluorosis with symptoms of joint pain, limited mobility, brittle bones, calcification of ligaments, bone and teeth abnormalities and mottles tooth enamel.

Irritation: None of the components are sensitizing to animals or humans.

Corrosivity: Phosphoric acid: Corrosive to rabbit skin and rabbit eyes. Hydrofluoric Acid: Corrosive to rabbit skin and rabbit eyes

Sensitization: Sodium Fluoride: Not sensitizing in Buehler test.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the European Substance Directive.

Mutagenicity: Phosphoric acid was negative in an in vitro mammalian cell gene mutation assay, in an in vitro mammalian chromosome aberration test and AMES test. The surfactant was negative in an in vitro genetic study.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Sodium Fluoride Oral rabbit LD50 - 320 mg/kg

Phosphoric Acid Oral rat LD50 1530 mg/kg, Skin rabbit LD50 2740 mg/kg

Hydrofluoric Acid: Inhalation rat LC50 1278 ppm/1 hr

Product ATE

Oral: 9,900 mg/kg

Dermal: 250,000 mg/kg

Inhalation: 500,000 ppm

Reproductive Toxicity Data: Sodium Fluoride: In a 75 day reproductive study with rats, doses of 4.5 ppm and 9.0 ppm showed a significant decrease in sperm count, sperm motility, sperm viability and sperm function. However, other animal studies, including two-generation studies, have not found alterations in serum hormone levels in male rats, testicular histopathology, sperm morphology, or fertility. None of the available laboratory animal studies examined reproductive toxicity at low fluoride doses. The inadequate human studies and conflicting animal studies do not allow for an assessment of the potential of fluoride to induce reproductive effects in humans. Animal studies have not found increases in the incidences of birth defects in the absence of maternal toxicity; at doses that caused maternal toxicity (decreases in body weight gain and food consumption), increases in abnormalities were found. Inorganic borates have been reported to cause adverse reproductive and developmental effects in laboratory animals given high oral doses. Phosphoric Acid: In a one generational study with rats, the offspring of adult male and female rats dosed with phosphoric acid did not display any negative effects resulting from the treatment.

Specific Target Organ Toxicity (STOT):

Single Exposure: Hydrogen fluoride is highly corrosive to rabbit skin. An 8% solution in a rabbit eye will cause reversible eye damage lasting 40-65 days.

Repeated Exposure: Repeated inhalation of 17 ppm hydrogen fluoride resulted in damage to the lungs, liver, and kidneys of animals, but similar inhalation of 8.6 ppm failed to elicit significant pathologic change in these tissues.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Sodium Fluoride: Rainbow Trout 96hr LC50: 317 ppm; Daphnia magna 48hr EC50:352 mg/kg
Phosphoric Acid: 96 hr LC50 Mosquitofish- 138 mg/L
Hydrofluoric acid: No data available

12.2 Persistence and Degradability:

Biodegradation is not applicable to inorganic substances such as sodium fluoride and hydrogen fluoride.

12.3 Bio-accumulative Potential:

The biological half-life of hydrogen fluoride is 12-24 hours.

12.4 Mobility in Soil:

No data available

12.5 Results of PBT and vPvB Assessment:

Not applicable

12.6 Other Adverse Effects:

None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product has a Reportable Quantity (RQ) of 33,333 lbs. based on the RQ for Sodium Fluoride of 1,000 lbs. Releases above the RQ must be reported to the National Response Center. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): All of the components of this product are listed on the TSCA inventory

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

**Superfund Amendments and Reauthorization Act (SARA) Title III Information:
SARA Section 311/312 (40 CFR 370) Hazard Categories:**

Immediate Hazard:	Yes
Pressure Hazard:	No
Delayed Hazard:	No
Fire Hazard:	No
Reactivity Hazard:	No

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
Hydrogen Fluoride	7664-39-3	<0.15

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:

Health: 2	Flammability: 0	Reactivity: 0
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Full text of Classification abbreviations used in Section 2 and 3:

C	Corrosive
T	Toxic
Xi	Irritant
R25	Toxic if swallowed.
R26/27/28	Causes serious eye irritation.
R32	Very toxic by inhalation, in contact with skin and if swallowed.
R34	Contact with acids liberates very toxic gas
R35	Causes burns.
R36/37/38	Irritating to eyes, respiratory system and skin.
R36/38	Irritating to eyes/skin
Acute Tox 3	Acute Toxicity Category 3
Acute Tox Cat 1	Acute Toxicity Category 1
Acute Tox Cat 2	Acute Toxicity Category 2
Eye Irrit Cat 2	Eye Irritant Category 2
Skin Corr Cat 1A	Skin Corrosive Category 1A
H300	Fatal if swallowed
H310	Fatal in contact with skin
H330	Fatal if inhaled
H314	Corrosive to skin and eyes
H315	Causes skin irritation

H319	Causes serious eye irritation
EU032	Contact with acids liberates very toxic gas

Supersedes: October 16, 2008

Date updated: November 30, 2015

Change Control Document #: DCN4682

Revision Summary: November 30, 2015: Converted MSDS to Reach SDS. Updated all sections.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Manufacturer disclaimer:

FOR DENTAL USE ONLY. The information and recommendations are taken from sources (raw material MSDS(s), SDS(s) and manufacturers knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.