

**ALPHA-PRO- sodium fluoride and hydrofluoric acid gel**  
**Dental Technologies, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**DTI APF - Vanilla Orange**

**Indications and Usage:**

Topical application of APF gel is indicated in the prevention of dental caries. This treatment is normally used two times per year and should not exceed four times per year.

**Contraindications:**

Hypersensitivity to fluoride.

**Warning:**

**Keep out of reach of children. Do not swallow.**

If swallowed during treatment, administer milk, limewater, or antacid. If larger dose is ingested (more than 1/4 ounce), contact poison control and immediately seek medical help. Contains FD&C Yellow No.6.

**Precautions:**

For professional use only. This product is not intended for home or unsupervised consumer use. Repeated use may cause dulling of porcelain and ceramic restorations.

**Adverse Reactions:**

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticaria, gastric distress, headache, and weakness.

**Dosage and Administration:**

After thorough prophylaxis, place gel in applicator tray (not more than 1/3 full). Thoroughly air-dry teeth and insert tray(s) in mouth. Gel may also be swab applied. Instruct patient to bite down slightly but firmly for one to four minutes. A slight chewing motion enhances coverage interproximally. Remove tray(s) and have patient expectorate excess gel. Instruct patient not to eat, drink or rinse for at least 30 minutes.

**How Supplied:**

A gel, one bottle contains up to 68 individual applications. Store at controlled room temperature 20°-25°C (68°-77°F).

Do not allow to freeze.

**☐Active Ingredients:**

1.23% w/w Fluoride Ion (0.79% from Sodium Fluoride and 0.44% from Hydrogen Fluoride) in 0.1

Molar Phosphoric Acid.

DENTAL TECHNOLOGIES

LINCOLNWOOD, ILLINOIS 60712 USA

[www.dentaltech.com](http://www.dentaltech.com)

**Questions or Comments?**

**Call: 1-800-835-0885 (US) or 1-847-677-5500**

PM-5098 Rev002

**Principal Display Panel**

DENTAL TECHNOLOGIES

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ALPHA-PRO® APF

TOPICAL GEL

60 SECOND TREATMENT

Acidulated Phosphate Fluoride

1.23% Fluoride Ion

Rx Only

Vanilla Orange

REF No. 009-4301-002

NET WEIGHT: 17.5 oz. (497g)

283



www.dentaltech.com

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### Vanilla Orange

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PM-5098 Rev002

sodium fluoride and hydrofluoric acid gel

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:55346-0943
<b>Route of Administration</b>	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.9 mg in 1 g
HYDROFLUORIC ACID (UNII: RGL5YE86CZ) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	4.4 mg in 1 g

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (Vanilla Orange)	<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55346-0943-1	497 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/01/2013	

**Labeler** - Dental Technologies, Inc. (148312838)

Revised: 12/2017

Dental Technologies, Inc.