

**ADVANCED FLUORIDE ANTICAVITY- sodium monofluorophosphate paste, dentifrice  
Personal Care Products, LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**ADVANCED FLUORIDE ANTICAVITY TOOTHPASTE - 9181**

**Active Ingredient  
Drug Facts**

Sodium Monofluorophosphate 0.76%

**Purpose**

Anticavity toothpaste

**Use**

Aids in the prevention of cavities

**Warnings**

If more than is used for brushing is accidentally swallowed get medical help or contact a poison control center right away.

**Keep out of reach of children**

Keep out of reach of children under 6 yrs of age.

**Directions**

adults and children 2 years. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist.

do not swallow

to minimize swallowing, use a pea-sized amount in children under 6 years old

supervise children's brushing until good habits are established

children under 2y ears: ask a dentist before use.

**inactive ingredients**

calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, saccharin sodium, sodium lauryl sulfate, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum.

**ADVANCED FLUORIDE ANTICAVITY product label**

CAVITY FIGHTING TOOTHPASTE

Distributed by:

Personal Care Products, LLC

Bingham Farms, MI 48025-2463

Made in China

Advanced Fluoride Anticavity Toothpaste

New Ultra Breath Freshener Stripe

Net Wt 6.4oz (181g)

Multi

Protection

Fights Cavities

Freshens Breath



ADVANCED ANTICAVITY TOOTHPASTE

**Fluoride**

Ultra BREATH FRESHENER STRIPE

<p><b>Drug Facts</b></p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><b>Active ingredient</b></td> <td style="width: 50%;"><b>Purpose</b></td> </tr> <tr> <td>Sodium monofluorophosphate 0.76%.....Anticavity toothpaste</td> <td></td> </tr> <tr> <td><b>Use</b></td> <td></td> </tr> <tr> <td colspan="2">aids in the prevention of cavities</td> </tr> <tr> <td><b>Warnings</b></td> <td></td> </tr> <tr> <td colspan="2">Keep out of reach of children under 6 yrs. of age.</td> </tr> <tr> <td colspan="2">If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> </table>	<b>Active ingredient</b>	<b>Purpose</b>	Sodium monofluorophosphate 0.76%.....Anticavity toothpaste		<b>Use</b>		aids in the prevention of cavities		<b>Warnings</b>		Keep out of reach of children under 6 yrs. of age.		If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.		<p><b>Drug Facts</b> (continued)</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ adults and children 2 yrs. and older: brush teeth thoroughly after meals or at least twice a day or as directed by a dentist</li> <li>■ do not swallow</li> <li>■ to minimize swallowing, use a pea-sized amount in children under 6 years old</li> <li>■ supervise children's brushing until good habits are established</li> <li>■ children under 2 yrs.: ask a dentist before use</li> </ul> <p><b>Inactive ingredients</b> calcium carbonate, calcium hydrogen phosphate, carboxymethyl cellulose, flavor, glycerin, hydrated alumina, hydrated silica, potassium sorbate, saccharin sodium, sodium lauryl sulfate, sorbitan monooleate, sorbitol, titanium dioxide, water, xanthan gum, FD&amp;C blue no.1.</p>
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**Personal Care**

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## ADVANCED FLUORIDE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9181
Route of Administration	DENTAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	1000 mg in 181 g

### Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALUMINUM OXIDE (UNII: LM26O6933)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9181-6	1 in 1 PACKAGE	07/24/2017	
1		181 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	07/24/2017	

**Labeler** - Personal Care Products, LLC (966155082)

**Registrant** - Personal Care Products, LLC (966155082)