

**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.

ADVANCED FLUORIDE ANTICAVITY TOOTHPASTE

Active Ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity toothpaste

Use

Aids in the prevention of cavities

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 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.

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



<p>ADVANCED ANTICAVITY TOOTHPASTE</p> <p>Fluoride</p> <p>Ultra BREATH FRESHENER STRIPE</p>	<p>Drug Facts</p> <table border="1"> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> <tr> <td>Sodium monofluorophosphate 0.76%.....Anticavity toothpaste</td> <td></td> </tr> <tr> <th>Use</th> <td>aids in the prevention of cavities</td> </tr> <tr> <th>Warnings</th> <td>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.</td> </tr> </table>	Active ingredient	Purpose	Sodium monofluorophosphate 0.76%.....Anticavity toothpaste		Use	aids in the prevention of cavities	Warnings	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>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> adults and children 2 yrs. 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 2 yrs.: ask a dentist before use <p>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, FD&C blue no.1.</p>	<p>Personal Care</p> <p>CAVITY FIGHTING TOOTHPASTE</p> <p>Distributed by: Personal Care Products, LLC Bingham Farms, MI 48025-2463 Made in China</p>  <p>0 48155 90819 2</p>
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ADVANCED FLUORIDE ANTICAVITY

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-0819
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM MONOFLUOROPHOSPHATE	0.76 g in 100 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 MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-0819-6	1 in 1 BOX		
1		181 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	01/24/2011	

Labeler - Personal Care Products, LLC (966155082)

Establishment

Name	Address	ID/FEI	Business Operations
Yangzhou Li'erkang Daily Used Chemicals Co., Ltd.		531075083	manufacture

Revised: 8/2011

Personal Care Products, LLC