

ADVANCED WHITENING ANTICAVITY FLUORIDE- 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 WHITENING ANTICAVITY FLUORIDE - 9223

Drug Facts

Active ingredient

Sodium Monofluorophosphate 0.76%

Purpose

Anticavity toothpaste

Uses

aids in the prevention of cavities

Warnings

If more than 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 2 yrs: 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 Whitening Anticavity product label

Personal Care™

Advanced Whitening Anticavity Fluoride Toothpaste

FRESH MINT

Fights Tarter Build-up

NET WT 6.4 OZ. (181 G)

Free Soft Toothbrush

Distributed by:

Personal Care Products, LLC

Troy, Michigan 48084 U.S.A.

Made in China



ADVANCED WHITENING ANTICAVITY FLUORIDE

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-9223
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)	
WATER (UNII: 059QF0K00R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-9223-6	1 in 1 BOX	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)