

SMILECARE - sodium monofluorophosphate paste, dentifrice
Shantou MContinents Trading Co, LTD

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.

Drug Facts

Inactive Ingredients: Dicalcium Phosphate, Water, Sorbitol, Silica, Glycerin,
Sodium Lauryl Sulfate, Flavor, Sodium Carboxymethyl Cellulose, Titanium Dioxide,
Hydroxypropyl Gum, Sodium Saccharine, Sodium Benzoate, Sodium Phosphate
Decahydrate, Limonene, Contains Sodium Mono-fluorophosphate: 1.0556ppm

Active Ingredient: Sodium Mono-fluorophosphate 0.080 %

Purpose: Anticavity toothpaste

Keep out of reach of children under 6 yrs.

Do not swallow

Directions: Brush your teeth at least twice a day as directed by dentist.

Anticavity toothpaste

TUBE LABEL



sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69108-001
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	64 mg in 8 g

Inactive Ingredients

Ingredient Name	Strength
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYDROXYPROPYL CELLULOSE (TYPE H) (UNII: RFW2ET671P)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE (UNII: E1W4N241FO)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69108-001-01	8 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2014	

Labeler - Shantou MContinents Trading Co, LTD (421359546)

Establishment

Name	Address	ID/FEI	Business Operations
Shantou MContinents Trading Co, LTD		421359546	manufacture(69108-001)

