BEEPROPOLIS - sodium monofluorophosphate paste, dentifrice Sinhwa Life Health 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

Propolis extract, Vitamin E, Stevioside, Xylitol, Silicon Dioxide,

Carboxymethylcellulose sodium, Xanthan Gum, D-Sorbitol solution,

Polyethylene glycol 4000, Cocamidopropyl betaine, Grapefruit seed extract,

Peppermint Oil, DL-Menthol, Water

Active Ingredients

Sodium monofluorophosphate

Purpose

Anticaries

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

Uses - Aids in the prevention of cavities

Directions

Adults and children 6 years of age and older - Brush teeth thoroughly preferably after each meal or at least twice a day

or as directed by a dentist or doctor

Children under 12 years of age - To minimize swallowing, use a pea sized amount and supervise brushing

until good habits are established

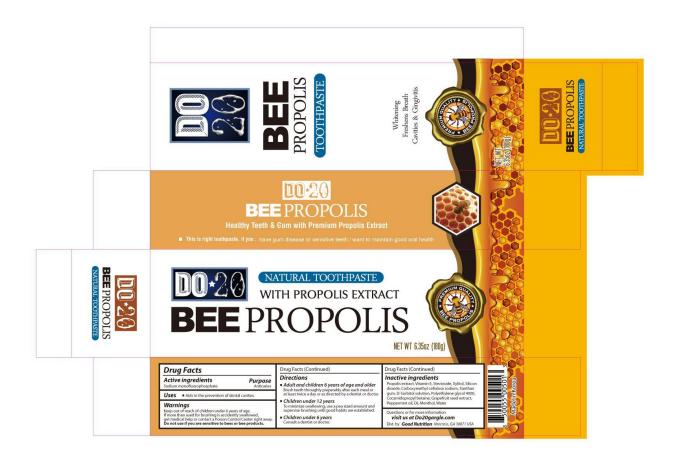
Children under 5 years of age - Consult a dentist or doctor

Warnings

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

If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Do not Use if you are sensitive to bees or bee products.



BEEPROPOLIS

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58964-101

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	100 mg in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
PROPOLIS WAX (UNII: 6 Y8 XYV2NOF)		
.ALPHATO COPHERO L (UNII: H4N8 55PNZ1)		
STEVIO SIDE (UNII: 0 YON5MXJ9 P)		
XYLITOL (UNII: VCQ006KQ1E)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CARBO XYMETHYLCELLULO SE SO DIUM (UNII: K679 OBS 311)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58964-101-01	1 in 1 CARTON		
1		180 g in 1 TUBE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	07/01/2013		

Labeler - Sinhwa Life Health Co Ltd (688492682)

Establishment				
Name	Address	ID/FEI	Business Operations	
Sinhwa Life Health Co Ltd		688492682	manufacture (58964-101)	

Revised: 7/2013 Sinhwa Life Health Co Ltd