

**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.*

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**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

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58964-101
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	100 mg in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>STEVIO SIDE</b> (UNII: 0YON5MXJ9P)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	

<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYETHYLENE GLYCOL 4000</b> (UNII: 4R4HF16D95)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>CITRUS PARADISI SEED</b> (UNII: 12F08874Y7)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>RACEMENTHOL</b> (UNII: YS08XHA860)	
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>Packaging</b>				
#	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		

<b>Marketing Information</b>			
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)

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

Revised: 7/2013

Sinhwa Life Health Co Ltd