SHOPKINS BRUSH BUDDIES- sodium fluoride paste Foshan Nanhai JiaChun Biology Engeneering 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.

Anticavity

Keep out of reach of children. In case of accidental digestion seek professional assistance or contact a poison control center immediately.

Active Ingredient Purpose

Sodium Fluoride 0.243% (0.15% w/v fluoride ion) Anticavity

Helps protect teeth and roots against cavities

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

If you accidentally swallow more than used for brushing, seek professional help or contact a poison control center immediately

Sorbitol, Silica, Aqua, PEG-32, Xylitol, Sodium Lauryl Sulphate, Flavor, Cellulose Gum, Benzyl Alcohol, Sodium Benzoate, Sodium Saccharin, Trisodium Phosphate, FD & C Blue #1, FD &C Red # 40

Adults and children 2 years and older:

Brush teeth thoroughly after meals or at least twice a day or use as directed by a dentist.

Do not swallow

To minimize swallowing use a pea-sized amount in children under 6 years of age.

Supervise children's brushing until good habits are established.

Children under 2 years of age: Ask a dentist.



SHOPKINS BRUSH BUDDIES sodium fluoride paste **Product Information Product** Type HUMAN OTC DRUG Item Code (Source) NDC:71106-002 DENTAL **Route of Administration Active Ingredient/Active Moiety Ingredient** Name **Basis of Strength** Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O) FLUORIDE ION 2.4 mg in 100 g **Inactive Ingredients** Strength **Ingredient** Name SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR) CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K6790BS311) SORBITOL (UNII: 506T60A25R) SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) WATER (UNII: 059QF0KO0R) .ALPHA.-(.ALPHA.-AMINOPROPYL)BENZYL ALCOHOL (UNII: S8TT5K3C8Y) POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A) XYLITOL (UNII: VCQ006KQ1E) SODIUM LAURYL SULFATE (UNII: 368GB5141J) SODIUM BENZOATE (UNII: OJ245FE5EU) SACCHARIN SODIUM (UNII: SB8ZUX40TY) **Product Characteristics** blue (F D & C Blue #1), red (FD &C Red #4) Color Score Shape Size Flavor **BUBBLE GUM** Imprint Code Contains Packaging # Item Code Package Description **Marketing Start Date Marketing End Date** 1 NDC:71106-002-01 119 g in 1 TUBE; Type 0: Not a Combination Product 0 1/11/20 17 **Marketing Information Marketing Category** Application Number or Monograph Citation **Marketing Start Date** Marketing End Date OTC monograph final part355 0 1/11/20 17

Establishment			
Name	Address	ID/FEI	Business Operations
Foshan Nanhai JiaChun Biology Engeneering Co., Ltd		527935253	manufacture(71106-002)

Revised: 1/2017

Foshan Nanhai JiaChun Biology Engeneering Co., Ltd