SHOPKINS BRUSH BUDDIES- sodium fluoride paste Ashtel Studios Inc.

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.

Shopkins Brush Buddies

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.

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sodium fluoride paste							
Product Information							
Product T ype	HUMAN OTC DRUG	Item Code (Source)			NDC:70108-005		
Route of Administration	DENTAL						
Active Ingredient/Active	Moiety						
		Basis of Strength		Strength			
SODIUM EL LIOPIDE (UNII) 87VC	FLUORIDE ION		-				
SODIOM FLOOKIDE (ONIL 021)	21474W7) (FLUORIDE ION - UNII:Q80	JVF04080)	FLOORIDE ION		2.4 mg m 100 g		
Inactive Ingredients	(14/4W/) (FLUORIDE ION - UNII:Q80	J V F U 4 U 8 U)	FLOORIDE ION		2.4 mg m 100 g		
	(14/4w7) (FLUORIDE ION - UNIEQ80 Ingredient Name	J V F U 4 U 8 U)	FLOORIDE ION				
Inactive Ingredients			FLOORIDE ION				
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI	Ingredient Name	50 QPHR)					
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI	Ingredient Name IC, DODECAHYDRATE (UNII: B7085	50 QPHR)			2.4 mg in 100 g Strength		
Inactive Ingredients SODIUM PHOSPHATE, TRIBASI CARBOXYMETHYLCELLULOS	Ingredient Name IC, DODECAHYDRATE (UNII: B7085 E SODIUM, UNSPECIFIED FORM (U	50 QPHR)					
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI CARBO XYMETHYLCELLULO S SORBITOL (UNII: 506T60A25R)	Ingredient Name IC, DODECAHYDRATE (UNII: B7085 E SODIUM, UNSPECIFIED FORM (U	50 QPHR)					
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI CARBO XYMETHYL CELLULO S SORBITOL (UNII: 506T60A25R) SILICA DIMETHYL SILYLATE (WATER (UNII: 059QF0K00R)	Ingredient Name IC, DODECAHYDRATE (UNII: B7085 E SODIUM, UNSPECIFIED FORM (U	50 Q PHR) UNII: K6 79 O B S 3 1 1)					
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI CARBO XYMETHYLCELLULO S SORBITOL (UNII: 506T60A25R) SILICA DIMETHYL SILYLATE (WATER (UNII: 059QF0KO0R)	Ingredient Name IC, DODECAHYDRATE (UNII: B7085 E SODIUM, UNSPECIFIED FORM (U UNII: EU2PSP0G0W) PYL)BENZYL ALCOHOL (UNII: S87	50 Q PHR) UNII: K6 79 O B S 3 1 1)					
Inactive Ingredients SODIUM PHO SPHATE, TRIBASI CARBOXYMETHYLCELLULOS SORBITOL (UNII: 506T60A25R) SILICA DIMETHYL SILYLATE (WATER (UNII: 059QF0K00R) .ALPHA(.ALPHAAMINOPROF	Ingredient Name IC, DODECAHYDRATE (UNII: B7085 E SODIUM, UNSPECIFIED FORM (U UNII: EU2PSP0G0W) PYL)BENZYL ALCOHOL (UNII: S87	50 Q PHR) UNII: K6 79 O B S 3 1 1)					

SODIUM BENZOATE (UNII: OJ245FE5EU)								
SACCHARIN SODIUM (UNII: SB8ZUX40TY)								
Product Characteristics								
Color	blue	e (F D & C Blue #1) , red (FD &C Red #4)	Score					
Shape			Size					
Flavor	BUI	3BLE GUM	Imprint Code					
Contains								
00	Packaging							
# Item Code		Package Description	Marketing Star	rt Date	Marketing End	Date		
1 NDC:70108-005-	-01	119 g in 1 TUBE; Type 0: Not a Combination Product	07/22/2016					
Marketing Information								
Marketing Categ	gory	Application Number or Monograph Citation	Marketing Sta	rt Date	Marketing End	Date		
OTC monograph fin	nal	part355	07/22/2016					

Labeler - Ashtel Studios Inc. (148689180)

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Ashtel Studios Inc.