

**BRUSHBUDDIES SHOPKINS ANTICAVITY FLUORIDE- sodium fluoride mouthwash**  
**Ashtel Studio 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.*

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Active Ingredient

Sodium Fluoride 0.05%

Purpose:

Anticavity

Uses:

Helps protect against cavities

Warnings:

If you accidentally swallow more than used for brushing, seek professional help or contact a Poison Control Center immediately

Keep out of reach of children

Directions:

- Adults and children 6 years and older:
- Use daily after your normal brush
- Shake well before each use
- Rinse or gargle for 30 seconds with 15 mL (3 teaspoonful) and then spit out
- Supervise children's brushing until good habits are established.
- Do not Swallow the rinse

Other Information

Store in cool and dry place away from direct sun light

Inactive Ingredients:

Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Xylitol, Flavor, Acesulfame, Sodium Benzoate, Saccharin Sodium, Rose Red 1

Brush Buddies®

**Shopkins**  
Once you get it... you can't stop!

**BUBBLE GUM FLAVOR**

**HELPS PREVENT CAVITIES!**

**•XYLITOL  
•ALCOHOL-FREE  
•SUGAR-FREE**



ANTICAVITY

**FLUORIDE MOUTHWASH**

16.9oz (500 mL)



# Brush Buddies®

## ANTICAVITY FLUORIDE MOUTHWASH

<b>Drug Facts:</b>
<b>Active Ingredient:</b> Sodium Fluoride: 0.05%
<b>Purpose:</b> Anticavity
<b>Use:</b> Helps protect against cavities.
<b>Warnings:</b> Keep out of reach of children. If accidentally swallowed, get medical help or contact Poison Control Center right away.
<b>Directions:</b> Adults and children 6 years of age and older: • Use daily after your normal brushing; rinse toothpaste from mouth prior to use. • Shake well before each use. • Rinse or gargle for 30 seconds with 15 mL (3 teaspoonful) and then spit out. • Do not swallow the rinse.
<b>Other Information:</b> Store in cool and dry place away from direct sun light.
<b>Inactive Ingredients:</b> Water, Glycerin, PEG-40 Hydrogenated Castor Oil, Xylitol, Flavor, Acesulfame, Sodium Benzoate, Sodium Saccharin, Rose Red 1

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www.brushbuddies.com  
FONTANA, CA 92336



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Item # 06784-24



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sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70108-502
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.0225 g in 100 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
XYLITOL (UNII: VCQ006KQ1E)	
ACESULFAME (UNII: MA3UYZ6K1H)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ROSE BENGAL AT (UNII: 1IID5XA5GB)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70108-502-01	500 g in 1 BOTTLE; Type 0: Not a Combination Product	12/03/2016	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part355	11/28/2016	

**Labeler** - Ashtel Studio Inc (148689180)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Foshan Nanhai JiaChun Biology Engineering Co., Ltd		527935253	manufacture(70108-502)

Revised: 12/2016

Ashtel Studio Inc