

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.

ALBÉA ART WORK APPROVAL FORM - TF1100

Customer Name: **Colgate** **ART WORK APPROVAL FORM - TF1100**

Product Name: **Shopkins, Bubble Gum Friends (P & B) 2018**

Tube Length: 143.00mm Tube Width: 38.00mm Tube Diameter: 20.00mm Total Height: 143.00mm Total Width: 38.00mm

OPTION 1
143.00mm

Drug Facts

Active Ingredient:
Sodium Fluoride 0.24% (2.4 mg/100 g)

Warnings:
Keep out of reach of children under 6 years of age. For use only in the mouth. Do not swallow. If swallowed, drink water. If irritation occurs, stop use and consult your dentist.

Directions:
Apply to the toothbrush and brush for 2 minutes, 2 times a day.

Other information:
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Prepared By: **Samuel** Date: **2018-03-28**

Checked By: **Samuel** Date: **2018-03-28**

Customer Sign: **Samuel**

SHOPKINS BRUSH BUDDIES

sodium fluoride paste

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70108-005 |
| Route of Administration | DENTAL | | |

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

| Ingredient Name | Strength |
|--|----------|
| SODIUM PHOSPHATE, TRIBASIC, DODECAHYDRATE (UNII: B70850QPHR) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311) | |
| SORBITOL (UNII: 506T60A25R) | |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W) | |
| WATER (UNII: 059QF0K00R) | |
| .ALPHA.-(.ALPHA.-AMINOPROPYL)BENZYL ALCOHOL (UNII: S8TT5K3C8Y) | |
| POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J) | |

SODIUM BENZOATE (UNI: OJ245FE5EU)

SACCHARIN SODIUM (UNI: SB8ZUX40TY)

Product Characteristics

| | | | |
|-----------------|---|---------------------|--|
| Color | blue (F D & C Blue #1) , red (FD &C Red #4) | Score | |
| Shape | | Size | |
| Flavor | BUBBLE GUM | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-------------------|--|----------------------|--------------------|
| 1 | NDC:70 108-005-01 | 119 g in 1 TUBE; Type 0: Not a Combination Product | 07/22/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355 | 07/22/2016 | |

Labeler - Ashtel Studios Inc. (148689180)

Revised: 12/2019

Ashtel Studios Inc.