

**ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash**  
**Nice-Pak Products, LLC**

-----  
**Swan 004 004.002/004AE**  
**Anticavity Fluoride Rinse**

**Claims**

KIDS ANTICAVITY ALCOHOL FREE FLUORIDE RINSE

**Active ingredient**

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

**Purpose**

Anticavity

**Use**

aids in the prevention of dental cavities

**Warnings**

for this product

**Keep out of reach of children.**

If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

**Directions**

Adults and children 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste.
- vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

## **Other information**

- store at room temperature

## **Inactive ingredients**

benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

## **Disclaimer**

\*This product is not manufactured or distributed by Chattem, Inc., distributor of Act<sup>®</sup> Bubblegum Blowout<sup>®</sup> Anticavity Fluoride Rinse.

## **Adverse reaction**

Distributed by: Consumer Product Partners, LLC,  
St. Louis, MO 63114, 1-888-593-0593

## **Principal display panel**

Sealed With Printed Neckband For Your Protection

SWAN<sup>®</sup>

KIDS

ANTICAVITY

ALCOHOL FREE

FLUORIDE RINSE

bubble gum

FLAVOR

Strong Cavity Protection

Compare to the active ingredient of Act<sup>®</sup> Bubblegum Blowout<sup>®</sup> Anticavity Fluoride Rinse\*

IMPORTANT:READ DIRECTIONS FOR PROPER USE

ADA Accepted

American Dental Association

Helps prevent cavities

18 FL OZ (1.12 PT) 532 mL

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION



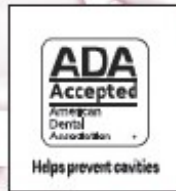
# KIDS ANTICAVITY ALCOHOL FREE FLUORIDE RINSE

## bubble gum FLAVOR

Strong Cavity Protection

Compare to the active ingredient of Act® Bubblegum Blowout® Anticavity Kids Fluoride Rinse\*

IMPORTANT: READ DIRECTIONS FOR PROPER USE



L0019934FB

### 18 FL OZ (1.12 PT) 532 mL

# KIDS ANTICAVITY ALCOHOL FREE FLUORIDE RINSE

## Drug Facts

Active ingredient	Purpose
Sodium fluoride 0.05% (0.02% w/v fluoride ion)	Anticavity

**Use** aids in the prevention of dental cavities

### Warning

**Keep out of reach of children.** If more than used for rinsing is accidentally swallowed, seek professional assistance or contact a Poison Control Center immediately.

### Directions

Adults and children 6 years of age and older:

- use once a day after brushing your teeth with a toothpaste
- vigorously swish 10 milliliters of rinse between your teeth for 1 minute and then spit out
- do not swallow the rinse
- do not eat or drink for 30 minutes after rinsing
- instruct children under 12 years of age in good rinsing habits (to minimize swallowing)
- supervise children as necessary until capable of using without supervision

Children under 6 years of age: consult a dentist or doctor

**Other information** ■ store at room temperature

**Inactive ingredients** benzyl alcohol, calcium disodium EDTA, cetylpyridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

**Questions? Call 1-888-593-0593**

\*This product is not manufactured or distributed by Chatter, Inc., distributor of Act® Bubblegum Blowout® Anticavity Kids Fluoride Rinse.

Distributed by: Consumer Product Partners, LLC, St. Louis, MO 63114, 1-888-593-0593



L0019934BB



## ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11344-004
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE CALCIUM DISODIUM</b> (UNII: 25IH6R4SGF)	
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DISODIUM DIHYDROGEN HYPOPHOSPHATE</b> (UNII: MR6TW8IQ9X)	
<b>POLOXAMER 407</b> (UNII: TUF2IWW3M2)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/29/2024	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	02/29/2024	

**Labeler** - Nice-Pak Products, LLC (119091520)

**Registrant** - Nice-Pak Products, LLC (119091520)

## Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(11344-004)