

**ANTICAVITY RINSE- sodium fluoride mouthwash**  
**Family Dollar Stores, Inc**

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**Family Wellness 004.002/004AE**  
**Anticavity Fluoride Rinse, Bubble Gum**

**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 year 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 year 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 Blow Out<sup>®</sup> Anticavity Kids Fluoride Rinse.

## **Adverse reaction**

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC

500 VOLVO PKWY

CHESAPEAKE, VA 23320 USA

NOT 100% SATISFIED?

Return within 30 days to the store of purchase for a refund (with receipt) or exchange.

MADE IN THE US WITH US AND FOREIGN COMPONENTS

## **Principal display panel**

IMPORTANT: read directions for proper use.

Sealed with printed neckband for your protection.

Do not use if band around cap is broken or missing.

FAMILY WELLNESS™

Compare to ACT<sup>®</sup> Bubblegum Blowout<sup>®</sup> Anticavity Kids Fluoride Rinse\*

Children's ANTICAVITY FLUORIDE RINSE

- Strong cavity protection
- Alcohol free
- Helps strengthen teeth
- Helps prevent cavities

BUBBLEGUM FLAVOR

18 FL OZ (1.12 PT) 532 mL

1

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**children's**

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L0021301FA



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L0021301BA

## ANTICAVITY RINSE

sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-004
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.2 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)	
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)	
<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:55319-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/02/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	08/02/2011	

**Labeler** - Family Dollar Stores, Inc (024472631)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(55319-004)