

**ANTICAVITY- sodium fluoride rinse**  
**Shopko Stores Operating Co.LLC**

*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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**Anticavity Fluoride Rinse, Bubble Gum**  
**004.001/004E**

**Active ingredient**

Sodium fluoride 0.055% (0.02% w/v fluoride ion)

**Purpose**

Anticavity rinse

**Use**

aids in the prevention of dental cavities

**Warnings**

**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 toothpaste
- remove cap
- pour 10 milliliters (10 mL mark on inside of cap); do not fill above the 10 mL mark
- 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, cetylpridinium chloride, disodium EDTA, disodium phosphate, flavor, poloxamer 407, polysorbate 80, propylene glycol, red 33, sodium benzoate, sodium phosphate, sodium saccharin, sorbitol, water

Sealed with printed neckband for your protection.

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

Manufactured by Vi-Jon, LLC.,

One Swan Dr., Smyrna, TN 37167

for ShopKo Stores Operating Co., LLC

[www.shopko.com](http://www.shopko.com)

For consumer questions call 1-888-593-05936

ShopKo Satisfaction Guaranteed By Refund Or Exchange

## **principal display panel**

ShopKo

Compare to the Active Ingredient of Act\*

Kids Anticavity Fluoride Rinse

Bubble Gum Flavor

Strong cavity protection

Helps strengthen teeth mm1.jpg

Helps prevent cavities

Alcohol Free

IMPORTANT: read directions for proper use

18 FL OZ (532 mL)

SHOPKO

\*COMPARE TO THE ACTIVE  
INGREDIENT OF ACTA

Kids  
Anticavity  
**Fluoride  
Rinse**

Bubble Gum Flavor

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

UN1125078

*IMPORTANT: read directions  
for proper use*

18 FL OZ (532 mL)

## ANTICAVITY

sodium fluoride rinse

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:37012-004
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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 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: TUF2IVW3M2)	
<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:37012-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/15/2011	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/15/2011	

**Labeler** - Shopko Stores Operating Co.LLC (023252638)

**Registrant** - Vi-Jon, LLC (790752542)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(37012-004)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(37012-004)