

**ANTICAVITY FLUORIDE RINSE- sodium fluoride rinse**  
**Topco Associates 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**  
**004.002/004AE**

**Active ingredient**

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

**Purpose**

Anticavity rinse

**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
- 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)
- 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

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

Distributed by: TOPCO ASSOCIATES LLC

7711 GROSS POINT ROAD, SKOKIE, IL 60077

QUESTIONS? 1-888-423-0139

### **principal display panel**

TOP CARE

Children's

Alcohol Free

Anticavity

Fluoride

Rinse

- Strong cavity protection
- Helps strengthen teeth
- Helps prevent cavities
- Freshens breath

Bubble Gum Flavor

COMPARE TO ACT

active ingredient

IMPORTANT: READ DIRECTIONS FOR PROPER USE

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

18 FL OZ (532 mL)

COMPARE TO ACT® BUBBLE GUM  
BLOWOUT® ANTICAVITY FLUORIDE RINSE\*



# BUBBLE GUM FLAVOR BLAST™

## Anticavity Fluoride Rinse

- Helps prevent cavities
- Alcohol free

IMPORTANT: Read directions for proper use.



18 FL OZ (1 PT 2 FL OZ) 532 mL

### ANTICAVITY FLUORIDE RINSE

sodium fluoride rinse

#### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:36800-004

Route of Administration		ORAL	
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Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.2 mg in 1 mL

  

Inactive Ingredients	
Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
CETYLPIRIDINIUM CHLORIDE (UNII: D9OM4SK49P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM ACID PYROPHOSPHATE (UNII: H5WD9LZUD)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

  

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM (Bubble Gum Flavor)	Imprint Code	
Contains			

  

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-004-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/08/2004	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	04/08/2004	

**Labeler** - Topco Associates LLC (006935977)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(36800-004)

## Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		088520668	manufacture(36800-004)

Revised: 1/2023

Topco Associates LLC