

**ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash**  
**Retail Business Services, 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, Mint**  
**213.002/213AE rev 2**

**Active Ingredient**

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

**Purpose**

Anticavity rinse

**Use**

aids in the prevention of dental cavities

**Warning**

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 the inside of cap); do not fill above the 10 mL mark
- vigorously swish 10 milliliters of rinse between your teeth for 1 minute 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 ingredient**

water, sorbitol, menthol, methyl salicylate, flavor, cetylpyridinium chloride, sodium saccharin, poloxamer 407, polysorbate 20, propylene glycol, sodium phosphate, disodium phosphate, calcium disodium EDTA, disodium EDTA, sodium benzoate, potassium sorbate, benzyl alcohol, green 3, yellow 5

## **Disclaimer**

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

DISTRIBUTED BY: FOODHOLD, U.S.A., LLC

Landover, MD 20785 1-877-846-9949

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Quality guaranteed or your money back.

## **Principal Panel Display**

CAREONE

Compare to Act Anticavity Fluoride Rinse\*

ANTICAVITY

FLUORIDE RINSE

MINT FLAVOR

Sealed With Printed Neckband For Your Protection

IMPORTANT: Read directions for proper use

18 FL OZ (532 mL)



## ANTICAVITY FLUORIDE RINSE

sodium fluoride mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72476-213
<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:Q80VPU408O)	FLUORIDE ION	0.2 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>MENTHOL</b> (UNII: L7T10EIP3A)	
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y)	
<b>CETYLPYRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	

<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)
<b>EDETATE CALCIUM DISODIUM MONOHYDRATE</b> (UNII: PKV6BFV915)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72476-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/24/2010	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	05/24/2010	

**Labeler** - Retail Business Services, LLC (967989935)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(72476-213)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(72476-213)

Revised: 5/2023

Retail Business Services, LLC