

**ANTICAVITY FLUORIDE RINSE- sodium fluoride mouthwash  
DEMOULAS SUPER MARKETS, INC**

*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 ingredients**

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

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

DISTRIBUTED BY: Demoulas Super Markets, Inc., 875 East Street, Tewksbury, MA 01876

## **principal display panel**

Sealed With Printed Neckband For Your Protection

"MORE FOR YOUR DOLLAR"

Market Basket

COMPARE TO ACT\*

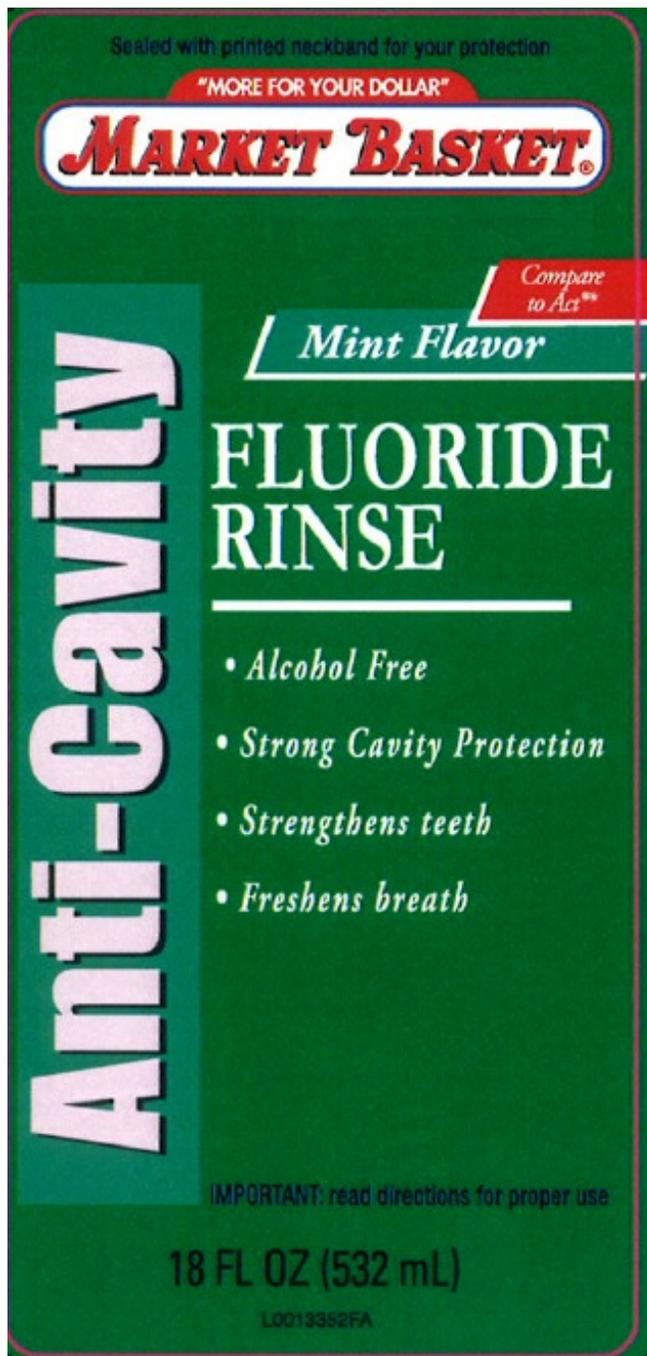
Mint Flavor

ANTI-CAVITY Fluoride Rinse

- Alcohol free
- Strong cavity protection
- Strengthens teeth
- Freshens breath

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:53942-213
<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>CETYLPIRIDINIUM 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 ANHYDROUS</b> (UNII: 8U5D034955)	
<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:53942-213-44	532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/25/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	08/25/2021	

**Labeler** - DEMOULAS SUPER MARKETS, INC (007869647)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(53942-213)

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Vi-Jon, LLC		790752542	manufacture(53942-213)

