

**SODIUM FLUORIDE- sodium fluoride mouthwash**  
**Demoulas Super Markets, Inc**

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**Market Basket 581.000/581AB**  
**Restoring Anticavity Fluoride Mouthwash**

**Claims**

Leaves your entire mouth feeling clean while it helps strengthen teeth and prevent tooth decay.

**Active ingredient**

Sodium fluoride 0.02% (0.009% w/v fluoride ion)

**Purpose**

Anticavity

**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, get medical help or contact a Poison Control Center right away.

**Directions**

Adults and children 6 years of age and older:

- use twice a day after brushing your teeth with a toothpaste
- vigorously swish 10 mL (2 teaspoonfuls) 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

## **Inactive ingredients**

water, alcohol (11%), sorbitol, poloxamer 407, propylene glycol, sodium benzoate, flavor, sodium phosphate, polysorbate 20, sodium saccharin, cetylpyridinium chloride, disodium phosphate, calcium disodium EDTA, blue 1

## **Adverse reaction**

\*This product is not manufactured or distributed by Chattem Inc., distributor of Act  
® Restoring Anticavity Mouthwash Cool Mint

DSP-TN-21091

DSP-MO-20087

DISTRIBUTED BY

DEMOULAS SUPER MARKETS, INC.

875 EAST STREET

TEWKSBURY, MA 01876

## **Principal Panel Display**

Sealed With Printed Neckband For Your Protection

MARKET BASKET ®

"MORE FOR YOUR DOLLAR"

Compare to Act ® Restoring Anticavity Fluoride Mouthwash\*

Restoring Anticavity

Fluoride Mouthwash

ANTICAVITY MOUTHWASH

Refreshing Mint

Restores enamel

Helps avoid tooth decay

Helps remineralize soft spots

Freshens breath

IMPORTANT: read directions for proper use.

33.8 FL OZ (1 L)

Sealed With Printed Neckband  
For Your Protection



Compare to Act® Restoring Anticavity Fluoride Mouthwash\*

**Restoring Anticavity Fluoride Mouthwash**  
ANTICAVITY MOUTHWASH

**Refreshing Mint**

- Restores enamel
- Helps avoid tooth decay
- Helps remineralize soft spots
- Freshens breath

IMPORTANT: read directions for proper use.

**33.8 FL OZ (1 L)**

L0020367FA

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**Drug Facts**

Active ingredient	Purpose
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L0020367BA

**SODIUM FLUORIDE**

sodium fluoride mouthwash

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53942-581
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)
<b>SODIUM PHOSPHATE</b> (UNII: SE337SVY37)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)
<b>CETYLPIRIDINIUM CHLORIDE</b> (UNII: D9OM4SK49P)
<b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F)
<b>EDETATE CALCIUM DISODIUM ANHYDROUS</b> (UNII: 8U5D034955)
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ALCOHOL</b> (UNII: 3K9958V90M)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53942-581-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/05/2023	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	06/05/2023	

**Labeler** - Demoulas Super Markets, Inc (007869647)

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(53942-581)