

**ANTICAVITY- sodium fluoride mouthwash**  
**United Natural Foods, Inc. dba UNFI**

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**Restoring Anticavity Fluoride Mouthwash**  
**581.000/581AC**

**Active ingredient**

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

**Purpose**

Anticavity

**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, 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

## **Tamper Evident Statement**

Sealed With Printed Neckband For Your Protection

## **Disclaimer**

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

## **Adverse reaction**

Like it or let us make it right.

That is our quality promise.

855-423-2630

DISTRIBUTED BY UNFI

PROVIDENCE, RI 02908 USA

## **Principal panel display**

compare to Act Restoring<sup>®</sup> Anticavity Fluoride Mouthwash Cool Mint active ingredient\*

EQUALINE<sup>®</sup>

restoring

anticavity

fluoride

mouthwash

- restores enamel
- helps avoid tooth decay

refreshing mint

IMPORTANT: READ DIRECTIONS FOR PROPER USE

33.8 FL OZ (1.05 QT) 1 L

compare to  
Act Restoring®  
Anticavity Fluoride  
Mouthwash Cool Mint  
active ingredient\*

**EQUALINE®**

restoring  
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- restores enamel
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refreshing mint

IMPORTANT: READ DIRECTIONS  
FOR PROPER USE.

LD019562FB

33.8 FL OZ (1.05 QT) 1L

**ANTICAVITY**

sodium fluoride mouthwash

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41163-581
<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:Q80VPU4080)	SODIUM FLUORIDE	0.2 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	

<b>PROPYLENE GLYCOL</b> (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>CETYLPYRIDINIUM 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)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41163-581-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/26/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	10/26/2020	

**Labeler** - United Natural Foods, Inc. dba UNFI (943556183)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(41163-581)

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(41163-581)

Revised: 11/2023

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