

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

*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**  
**971.001-971AB**

**Active Ingredient**

Sodium fluoride 0.02% (0.01% 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 immediately

**Directions**

Adults and children 6 years of age and older:

- use twice daily 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

**Other information**

- store at room temperature 20° - 25°C (68° - 77°F)
- cold weather may temporarily cloud this product

**Inactive ingredients**

water, sorbitol, propylene glycol, poloxamer 407, sodium lauryl sulfate, flavor, sodium benzoate, phosphoric acid, eucalyptol, methyl salicylate, thymol, sodium saccharin, menthol, disodium phosphate, sucralose, Mentha viridis (spearmint) leaf oil, Mentha piperita (peppermint) oil, red 40, blue 1

Sealed With Printed Neckband For Your Protection

Do Not Use If Band Around Cap Is Broken or Missing.

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributor or Listerine Total Care Zero Alcohol Anticavity Fresh Mist Mouthwash.

Like it or let us make it right.

That's our quality promise.

855-423-2630

DISTRIBUTED BY UNFI PROVIDENCE, RI 02908 USA

**Principal panel display**

compare to Listerine Total Care Zero Alcohol Mouthwash active ingredient\*

EQUALINE

Fluoride Anti-Cavity

Mouthwash

Sodium Fluoride and Acidulated

Phosphate Topical Solution

- alcohol-Free
- helps strengthen teeth to fight cavities
- helps restore enamel
- kills germs that cause bad breath

IMPORTANT: read directions for proper use.

FRESH MINT

1 L (33.8 FL OZ)

compare to  
**Listerine® Total Care**  
**Zero Alcohol Mouthwash**  
 active ingredient\*

**EQUALINE®**

fluoride  
**anticavity  
 mouthwash**

sodium fluoride and acidulated  
 phosphate topical solution

- *alcohol free*
- *helps strengthen teeth  
 fight cavities*
- *helps restore enamel*
- *kills germs that  
 cause bad breath*



**IMPORTANT:** read directions for proper use.

**fresh mint**

L0021054FA

**1L (33.8 FL OZ)**

**ANTICAVITY**

sodium fluoride rinse

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:41163-971 |
| <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      | 0.1 mg in 1 mL |

**Inactive Ingredients**

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

|  |
|--|
| <b>water</b> (UNII: 059QF0KO0R)                                |
| <b>SORBITOL</b> (UNII: 506T60A25R)                             |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)                     |
| <b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)                        |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)                      |
| <b>PHOSPHORIC ACID</b> (UNII: E4GA8884NN)                      |
| <b>eucalyptol</b> (UNII: RV6J6604TK)                           |
| <b>methyl salicylate</b> (UNII: LAV5U5022Y)                    |
| <b>thymol</b> (UNII: 3J50XA376E)                               |
| <b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)                     |
| <b>SODIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: 22ADO53M6F) |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)                            |
| <b>SPEARMINT OIL</b> (UNII: C3M81465G5)                        |
| <b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)                       |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                  |
| <b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)                  |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:41163-971-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/01/2021           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part355                                  | 10/01/2021           |                    |

**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(41163-971) |

### Establishment

| Name        | Address | ID/FEI    | Business Operations    |
|-------------|---------|-----------|------------------------|
| Vi-Jon, LLC |         | 088520668 | manufacture(41163-971) |