# ANTICAVITY- sodium fluoride rinse OLD EAST MAIN CO.

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Rexall 971.001-971AB Anticavity Fluoride Rinse

#### TAMPER EVIDENT STATEMENT

Sealed with printed neckband for your protection.

#### **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 right away.

#### **Directions**

Adults and children 6 years of age and older:

- use twice daily after brushing your teeth with a toothpaste
- vigorously swish 10 mL of rinse between your teeth for 1 miute 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

#### **Disclaimer**

Since 1903 Rexall® is a registered trademark of Rexall Sundown, Inc.

\*This product is not intended to replace brushing or flossing

#### **Adverse Reaction**

100% Satisfaction Guaranteed

If you're not satisfied with this product for any reason, please call us so we can make you 100% satisfied.

(888)309-9030

DISTRIBUTED BY OLD EAST MAIN CO.

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

#### principal panel display

Since 1903

Rexall

Fluoride Anti-Cavity

Mouthwash

Sodium Fluoride and Acidulated

Phosphate Topical Solution

Alcohol-Free

#### 6 BENEFITS

- Freshens breath
- Restores enamel
- Helps strengthen teeth to fight cavities
- Kills bad breath germs
- Burn free
- Cleans the entire mouth\*

IMPORTANT: read directions for proper use.

FRESH MINT

1 L (1.05 QT) 33.8 FL OZ



#### **ANTICAVITY**

sodium fluoride rinse

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:55910-971

**Route of Administration** ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080) FLUORIDE ION 0.1 mg in 1 mL

| Inactive Ingredients                                    |          |
|---|----------|
| Ingredient Name   | Strength |
| WATER (UNII: 059QF0KO0R)                                |          |
| SORBITOL (UNII: 506T60A25R)                             |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                     |          |
| POLOXAMER 407 (UNII: TUF2IVW3M2)                        |          |
| SODIUM LAURYL SULFATE (UNII: 368GB5141J)                |          |
| SODIUM BENZOATE (UNII: OJ245FE5EU)                      |          |
| PHOSPHORIC ACID (UNII: E4GA8884NN)                      |          |
| EUCALYPTOL (UNII: RV6J6604TK)                           |          |
| METHYL SALICYLATE (UNII: LAV5U5022Y)                    |          |
| THYMOL (UNII: 3J50XA376E)                               |          |
| SACCHARIN SODIUM (UNII: SB8ZUX40TY)                     |          |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)            |          |
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                            |          |
| SPEARMINT OIL (UNII: C3M81465G5)                        |          |
| PEPPERMINT OIL (UNII: AV092KU4JH)                       |          |
| FD&C RED NO. 40 (UNII: WZB9127XOA)                      |          |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD)                      |          |

| Packaging |                    |   |                         |                       |  |  |
|-----------|--------------------|---|-------------------------|-----------------------|--|--|
| # 1       | tem Code           | Package Description   | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| 1 NI      | DC:55910-<br>71-86 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 10/01/2021              |                       |  |  |

| Marketing Information |   |                         |                       |  |  |
|-----------------------|---|-------------------------|-----------------------|--|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |  |
| OTC Monograph Drug    | M021  | 10/01/2021              |                       |  |  |
|                       |   |                         |                       |  |  |

### Labeler - OLD EAST MAIN CO. (068331990)

## **Registrant -** Consumer Product Partners, LLC (119091520)

| Establishment                  |         |           |                            |  |  |  |
|--------------------------------|---------|-----------|----------------------------|--|--|--|
| Name                           | Address | ID/FEI    | <b>Business Operations</b> |  |  |  |
| Consumer Product Partners, LLC |         | 119091514 | manufacture(55910-971)     |  |  |  |

Revised: 9/2024 OLD EAST MAIN CO.