

MOUTH RINSE- sodium fluoride mouthwash
Topco Associates LLC

Top Care 163.005/163AG
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

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 under 12 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 anything 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 12 years of age: consult a dentist or doctor

Other information

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

Inactive ingredients

water, alcohol (21.6 %v/v), sorbitol, poloxamer 407, eucalyptol, flavor, methyl salicylate, menthol, phosphoric acid, sodium saccharin, thymol, disodium phosphate, sucralose, red 40, blue 1

Disclaimer

*This product is not manufactured or distributed by Kenvue, Inc., distributor of Listerine® Total Care Fresh Mint Anticavity Mouthwash.

ADVERSE REACTION

DISTRIBUTED BY TOPCO ASSOCIATES LLC, ITASCA, IL 60143

TOPCO VIJA0219 QUESTIONS? 1-888-423-0139 topcare@topco.com

TOPCO VIJA1024 QUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

DSP-TN-21091

DSP-MO-20087

Scan her for more information or call 1-888-423-0139

QUALITY GUARANTEED

PRINCIPAL DISPLAY PANEL

COMPARE TO LISTERINE® TOTAL CARE FRESH MINT ANTICAVITY MOUTHWASH*

TopCare®

everyday

FLUORIDE

Anticavity

Mouthwash

SODIUM FLUORIDE AND ACIDULATED PHOSPHATE TOPICAL SOLUTION

EUCALYPTUS MINT

6 Benefits

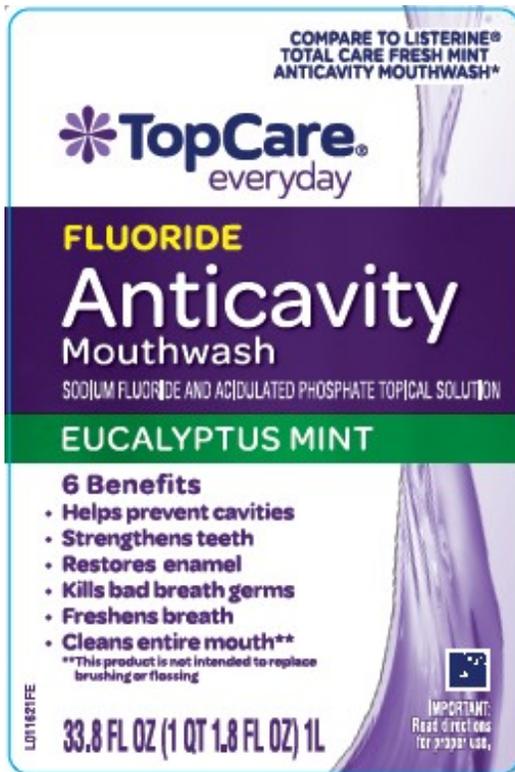
- Helps prevent cavities

- Strengthens teeth
- Restores enamel
- Kills bad breath germs
- Freshens breath
- Cleans entire mouth**

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

IMPORTANT: Read directions for proper use.

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



MOUTH RINSE

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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)	

ALCOHOL (UNII: 3K9958V90M)
SORBITOL (UNII: 506T60A25R)
POLOXAMER 407 (UNII: TUF2IVW3M2)
EUCALYPTOL (UNII: RV6J6604TK)
METHYL SALICYLATE (UNII: LAV5U5022Y)
MENTHOL (UNII: L7T10EIP3A)
PHOSPHORIC ACID (UNII: E4GA8884NN)
SACCHARIN SODIUM (UNII: SB8ZUX40TY)
THYMOL (UNII: 3J50XA376E)
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)
SUCRALOSE (UNII: 96K6UQ3ZD4)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-001-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/30/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	12/30/2010	

Labeler - Topco Associates LLC (006935977)

Registrant - Nice-Pak Products, LLC (119091520)

Establishment			
Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(36800-001)