ANTICAVITY- sodium fluoride rinse Liberty Procurement, Inc

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.

Burn-Free Fluoride Anti-Cavity Mouthwash 971.001/971AB

Active ingredient

Sodium fluoride 0.02% (0.01% w/v fluoride ion)

Purpose

Anticavity rinse

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 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 controlled 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

This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributer of Listerine Total Care Zero Alcohol Anticavity Fresh Mint Mouthwash

SATISFACTION GUARANTEED

or your money back

Distributed by

Liberty Procurement Co. Inc.

Union, NJ 07083 USA

Visit us at: www.facevalues.com

Principal Panel Display

CORE VALUES

Compare to Listerine

Zero Alcohol Anticavity

Fluoride Anti-Cavity

MOUTHWASH

Sodium Fluoride and Acidulated Phosphate Topical Solution

anticavity Mouthwash

Helps strengthen teeth to fight cavities

Restores enamel

Kills bad breath germs

Alcohol Free

IMPORTANT:

Read directions for proper use.

Fresh Mint

1 Liter (QT 1.8 FL OZ)

Sealed With Printed Neckband For Your Protection



Fluoride Anti-Cavity MOUTHWASH

Sodium Fluoride and Acidulated Phosphate Topical Solution

Anticavity Mouthwash

Helps strengthen teeth to fight cavities

Restores enamel

Kills bad breath germs

Alcohol Free

IMPORTANT: Read directions for proper use.

1 LITER (1 QT 1.8 FL OZ)



L0020791FA

Fresh

ANTICAVITY

sodium fluoride rinse

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63940-971

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Sodium fluoride (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	.2 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 (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)	

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940- 971-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/03/2022	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part355	11/03/2022	

Labeler - Liberty Procurement, Inc (804085293)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63940-971)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63940-971)

Revised: 9/2023 Liberty Procurement, Inc