ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Big Lots

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.

Spring Mint Antiseptic Mouthrinse 072.003/072AN

Active ingredients

Eucalyptol 0.092% Menthol 0.042% Methyl salicylate 0.060% Thymol 0.064%

Purpose

Antigingivitis, antiplaque

Use

helps control plaque that leads to gingivitis

Warnings

for this product

Do not use

if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediately. These may be signs of periodontitis, a serious form of gum disease.

Stop use and ask a dentist if

gingivitis, bleeding, or redness persists for more than 2 weeks.

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

- do not swallow
- not intended to replace brussing or flossing

adults and childen 12 years of age and older - vigorously swish 20 mL (2/3 FL OZ or 4 teaspoonfuls) between teeth twice a day for 30 seconds then spit out

children under 12 years of age - consult a dentist or doctor

other information

cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59° - 77° F)

Inactive ingredients

water, alcohol 21.6%, sorbitol, poloxamer 407, benzoic acid, sodium saccharin, flavor, sodium citrate, yellow 10, green 3

Questions or comments

1-888-593-0593

*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Fresh Burst Listerine Antiseptic Mouthwash

Manufactured for Big Lots

By Vi-Jon, LLC

8515 Page Avenue

St. Louis, MO 63114

principal display panel

SOUNDBODY

Compare to active

Ingredients in Freshburst

Listerine Antiseptic

ANTISEPTIC

MOUTHRINSE

Antigingivitis/Antiplaque

Kills Germs That Cause:

- Plaque
- Bad Breath
- Gingivitis Gum Disease

SPRING MINT

1.5 L (1 QT 1 PT 2.7 FL OZ) 50.7 FL OZ



ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-072	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - METHYL SALICYL		0.60 mg in 1 mL	
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E) THYMOL		0.64 mg in 1 mL	
Inactive Ingredients			
Ingredient Name		Strength	

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WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594- 072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2015	
2	NDC:50594- 072-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2015	

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC monograph not final	part356	04/30/2015	

Labeler - Big Lots (017885351)

Registrant - Vi-Jon, LLC (790752542)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		790752542	manufacture(50594-072)	

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi-Jon, LLC		088520668	manufacture(50594-072)	

Revised: 1/2023

Big Lots