

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.

Sound Body 664.003 -664AU

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

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

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

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

- this rinse is not intended to replace brushing or flossing

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 solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, FD&C green no.3

Questions or comments

1-888-593-0593

Disclaimer

This product is not manufactured or distributed by Johnson & Johnson Healthcare products, distributor of Cool Mint Listerine Antiseptic Mouthwash

Adverse Reactions

Manufactured By; Vi-Jon, Inc.

for Big Lots

8515 Page Ave

St. Louis, MO 63114

V#425040

ITEM 664

principal display panel

SOUND BODY

Compare to active

Ingredients in Cool Mint

Listerine Antseptic

ANTISEPTIC

Mouthrinse

Antigingivitis/Antiplaque

Kills Germs That Cause:

- Plaque
- Bad Breath
- Gingivitis Gum Disease

BLUE MINT

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

 **SOUNDBODY™**

Compare to active
Ingredients in Cool Mint
Listerine Antiseptic*

ANTISEPTIC
Mouthrinse
Antigingivitis/Antiplaque

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BLUE MINT 

1.5 L (1 QT 1 PT 2.7 FL OZ) 50.7 FL **OZ** L0014213FC

ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50594-664
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 - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50594-664-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2015	
2	NDC:50594-664-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End 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(50594-664)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(50594-664)

Revised: 5/2022

Big Lots