

**ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyol salicylate,
thymol mouthwash
Marc Glassman, 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.

**Spring Mint Antiseptic Mouthrinse
072.003/072AL rev 2/072AN**

Other Safety Information

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

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

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; do not swallow

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, poloxamer 407, benzoic acid, sodium saccharin, flavor, sodium citrate, yellow 10, green 3

*This product is not manufactured or distributed by Johnson & Johnson Corporation, distributor of FreshBurst® Listerine® Antiseptic Mouthwash.

Distributed by:

Marc Glassman, Inc

West 130th Street

Cleveland, OH 44130

DSP-TN-15000

DSP-MO-34

principal display panel

Marc's

*Compare to FreshBurst® Listerine® Mouthwash

Antiseptic Mouthwash

Antigingivitis/Antiplaque

HELPS REDUCE PLAQUE AND REFRESH BREATH

Kills Germs that Cause

- Bad Breath
- Plaque
- Gingivitis Gum Disease

Spring Mint Flavor

1.5L (1.58 QT) 50.7 FL OZ



*Compare to FreshBurst®
Listerine® Mouthwash

Antiseptic Mouthwash

ANTINGINGIVITIS / ANTIPLAQUE



Kills Germs That Cause

- Bad Breath
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- Gingivitis Gum Disease



L0018377FB

1.5 L (1.58 QT) 50.7 FL OZ

ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyol salicylate, thymol mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68998-072
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: BV616604TK) (EUCALYPTOL (UNII: BV616604TK))	EUCALYPTOL	0.92 mg

EUCALYPTOL (UNII: RV6J66041R) (EUCALYPTOL - UNII:RV6J66041R)	EUCALYPTOL	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 SOLUTION (UNII: 8KW3E207O2)	
POLOXAMER 407 (UNII: TUF21VW3M2)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68998-072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/22/2019	

Labeler - Marc Glassman, Inc (094487477)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(68998-072)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(68998-072)

