

**ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash**  
**Chain Drug Manufacturing Assn**

*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.*

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**Drug Facts Quality Choice 072.003/072AN**

**Active ingredients**

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

**Purpose**

Antigingivitis, antiplaque

**Use**

help 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; 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, poloxamer 407, benzoic acid, sodium saccharin, flavor, sodium citrate, D&C yellow no. 10, FD&C green no.3

### **Disclaimer**

This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of FreshBurst Listerine Antiseptic Mouthwash.

### **Adverse Reactions**

Distributed by C.D.M.A., Inc

43157 W 9 Mile Rd

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 800-93-2362

### **principal display panel**

QC

QUALITY

CHOICE

Compare to FreshBurst

LISTERINE

Antiseptic Mouth Rinse

Antigingivitis/Antilauqu

Kills Germs That Cause:

Bad Breath

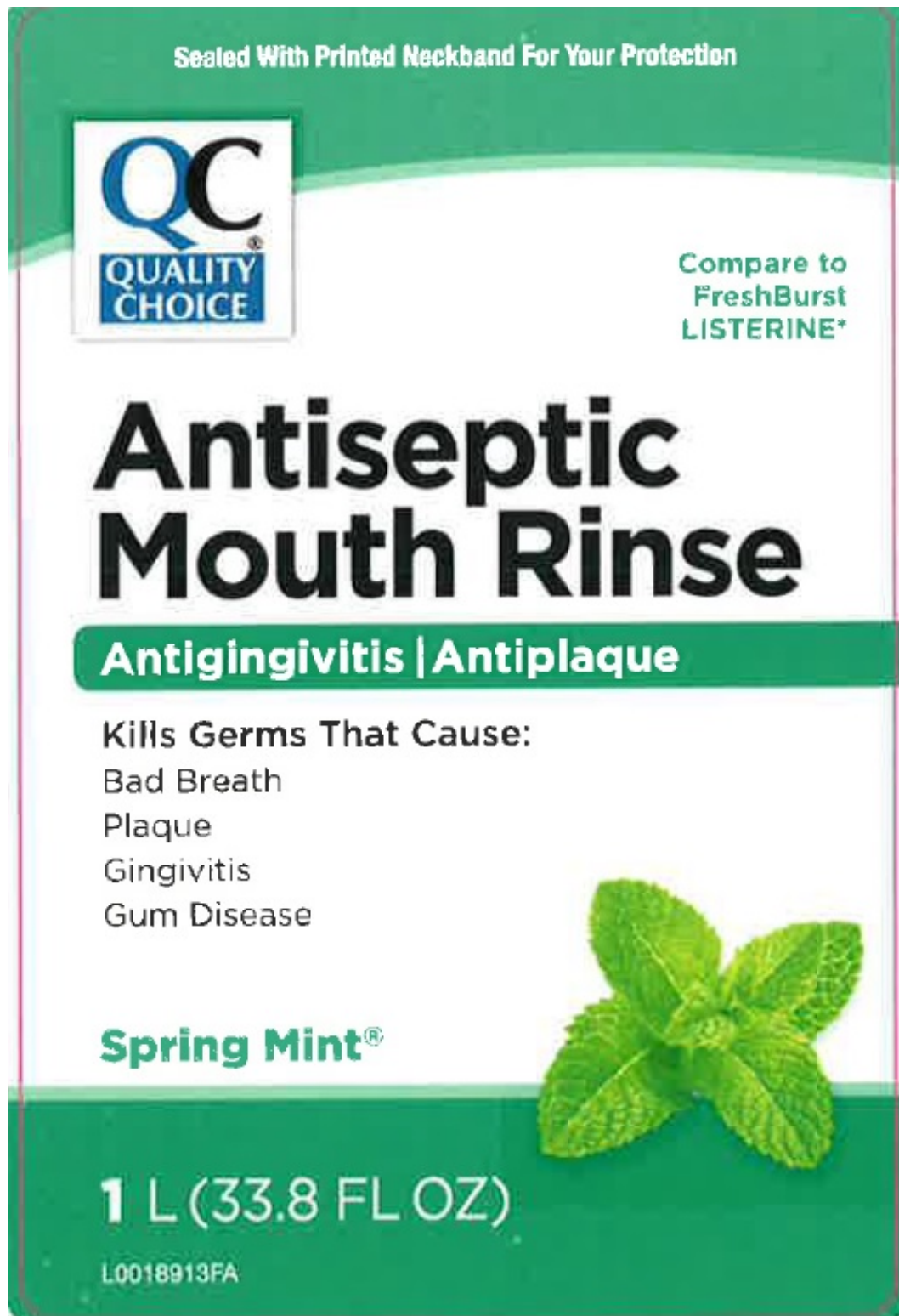
Plaque

Gingivitis

Gum Disease

Spring Mint

1 L (33.8 FL OZ)



## ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-214
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>EUCALYPTOL</b> (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	0.92 mg in 1 mL
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.42 mg in 1 mL
<b>METHYL SALICYLATE</b> (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL
<b>THYMOL</b> (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLOXAMER 407</b> (UNII: TUF2IVW3M2)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-214-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/28/2010	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/28/2010	

**Labeler** - Chain Drug Manufacturing Assn (011920774)

**Registrant** - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(63868-214)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(63868-214)

Revised: 4/2022

Chain Drug Manufacturing Assn