# ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyl salicylate, thymol mouthwash Shopko

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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# 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**

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. It antiseptic properties are not affected. Store at room temperature ( $59^{\circ}$  -  $77^{\circ}$  F)

## **Inactive ingredients**

water, alcohol 21.6%, sorbitol solution, flavor, poloxamer 407, benzoic acid, sodium saccharin, 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 Fresh Burst Listerine

#### **Adverse Reactions Section**

Distributed by Shopko Stores Operating CO., LLC Green Bay, WI, 54307
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## principal display panel

**SHOPKO** 

COMPARE TO THE ACTIVE INGREDIENTS OF LISTERINE

**Antiseptic** 

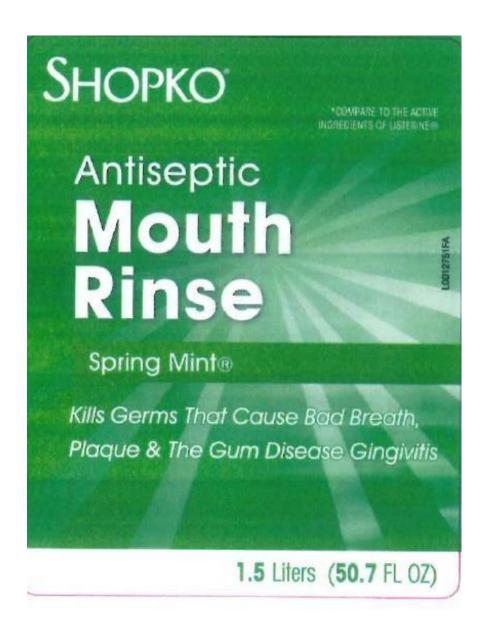
Mouth

Rinse

Spring Mint

Kills Germs That Cause Bad Breath, Plaque & The Gum Disease Gingivitis

1.5 Liters (50.7 FL OZ)



#### **ANTISEPTIC MOUTH RINSE**

Product Information

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-072		

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 - UNII:0414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL	
TUVMOI (IINIII- DIENVADTEEL (TUVMOI IINIII-DIENVADTEEL	TUVMOI	0.64 mg	

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 CITRATE (UNII: 1Q73Q2JULR)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)				

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	MINT (Spring Mint)	Imprint Code	
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:37012- 072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008		
2	NDC:37012- 072-13	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008		
3	NDC:37012- 072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/08/2008		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/08/2008	

## **Labeler -** Shopko (023252638)

# Registrant - Vi Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(37012-072)

Establishment				
Name	Address	ID/FEI	Business Operations	
Vi Jon, LLC		088520668	manufacture(37012-072)	

Revised: 1/2023 Shopko