# ANTISEPTIC MOUTH RINSE- eucalyptol. menthol, methyl salicylate, thymol mouthwash Wakefern Food Corporation

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**

### 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 Warnings

#### 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 (59I - 77IF)

#### **Inactive ingredients**

water, alcohol 21.6%, sorbitol, poloxamer 407, benzoic acid, flavoring, sodium saccharin, flavor,

sodium citrate, citric acid, D+C yellow no. 10, FD+C green no.3

#### **ADA Statement**

The ADA Council on Scientific Affairs Acceptance of Shop Rite Spring Mint Antiseptic Mouth Rinse is based on its finding that the product is effective in helping prevent and reduce gingivitis and plaque above the gumline, when used as directed.

#### **Dis claimer**

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

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

#### **Adverse Reactions**

Distributed By:

Wakefern Food Corp

5000 Riverside Drive

Keasbey, NJ 08832

Call: 1-800-SHOPRITE

Email: www.shoprite.com

### principal display panel

Compare to the Active Ingredients of Listerine

ShopRite

Antiseptic

Mouth Rinse

Helps to kill germs that cause plaque, gingivitis and bad breath

FRESH MINT

**ADA** 

Accepted

American

Dental

Association

Sealed With Printed Neckband For Your Protection

1.5 L (50.7 FL OZ)



# ANTISEPTIC MOUTH RINSE

eucalyptol. menthol, methyl salicylate, thymol mouthwash

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-072		
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:O414PZ4LPZ)	METHYL SALICYLATE	0.60 mg in 1 mL	
THYMOL (UNII: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E)	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: 8 SKN0 B0 MIM)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		

I	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	NDC:41190-072-	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/1999			
	NDC:41190-072-	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/1999			
	NDC:41190-072-	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/28/1999			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part356	05/28/1999		

# Labeler - Wakefern Food Corporation (069722418)

# **Registrant -** Vi-Jon (790752542)

Revised: 4/2020 Wakefern Food Corporation