

## **ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash**

### **Wakefern Food Corp**

*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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### **Mouthrinse**

**124**

### **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**

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 the rinse

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, sucralose and/or sodium saccharin, sodium benzoate, propylene glycol alginate, FD&C yellow no. 6, FD&C blue no. 1

\*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Listerine

Distributed By

Wakefern Food Corp.

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Keasbey, NJ 08832

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124.000/124AE

**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

VANILLA MINT

Sealed With Printed Neckband For Your Protection

1L (33.8 FL OZ)

Compare to the Active Ingredients of LISTERINE®



# Antiseptic MOUTH RINSE

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

**VANILLA MINT**



Sealed With Printed Neckband For Your Protection

1 L (33.8 FL OZ)

L0004575FB

## ANTISPETIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41190-124
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)				
PROPYLENE GLYCOL ALGINATE (UNII: 26CD3J2R0C)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-124-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/04/2009	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part356	08/04/2009	

**Labeler** - Wakefern Food Corp (069722418)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(41190-124)

Revised: 5/2020

Wakefern Food Corp