ANTISEPTIC MOUTH RINSE - eucalyptol mouthwash
Vi-Jon

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.

Drug Facts

Active ingredients
Eucalyptol 0.092%, Menthol 0.042%
Methyl salicylate 0.060%, Thymol 0.064%

Purpose
Antiginvitis, Antiplaque

Use helps control plaque that leads to gingivitis

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 • this rinse is not intended to replace brushing or flossing

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

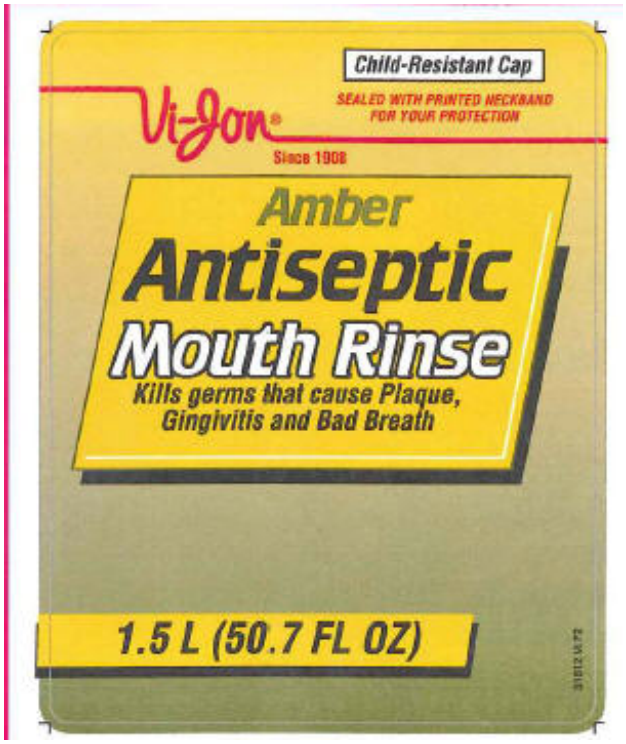
Other information cold weather may cloud this product. Its antiseptic properties are not affected. Store at room temperature (59□-77□F)

Inactive ingredients water, alcohol 26.9%, benzoic acid, poloxamer 407, sodium benzoate, caramel

DSP-TN-15000
DSP-MO-34
SDS-TN-15012

Distributed by:
Vi-Jon
St. Louis, Missouri 63114
Questions 1-888-593-0593

Child-Resistant Cap
SEALED WITH PRINTED NECKBAND
FOR YOUR PROTECTION
Amber
Antiseptic
Mouth Rinse
Kills germs that cause Plaque,
Gingivitis and Bad Breath
1.5 L (50.7 FL OZ)



ANTISEPTIC MOUTH RINSE

eucalyptol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11344-318
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	.092 kg in 100 L
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.042 kg in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	.060 kg in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	.064 kg in 100 L

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-318-86	1 L in 1 BOTTLE, PLASTIC		
2	NDC:11344-318-69	.25 L in 1 BOTTLE, PLASTIC		
3	NDC:11344-318-12	1.5 L in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/04/2001	

Labeler - Vi-Jon (150931459)

Registrant - Vi-Jon (150931459)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		150931459	manufacture

Revised: 1/2011 Vi-Jon