

**ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash**

**Hy-Vee Inc**

*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**

**Safety Seal**

SEALED WITH PRINTED NECKBAN FOR YOUR PROTECTION

**Active Ingredients**

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

**Purpose**

Antigingivitis, Antiplaque

**use**

Use helps control plaque that leads to gingivitis

**Warnings**

**Warnings**

**Do not use**

**Don't use** if you have painful or swollen gums, pus from the gum line, loose teeth or increased spacing between the teeth. See your dentist immediatel. These may be signs of periodontitis, a serious form of gum disease.

**Stop use and ask a dentist**

**Stop use and ask a dentist if** gingivitis, bleeding, or redness persists for more than 2 weeks

**Keep out of reach of children**

**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**

**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**

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

### **Inactive ingredients**

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

### **ADA Council Statement**

The ADA Council on Scientific Affairs Acceptance of Hy-Vee original 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.

### **Disclaimer**

This product is not manufactured or distributed by Johnson + Johnson Healthcare products, distributor of Listerine

### **Adverse Reaction**

DISTRIBUTED BY HY-VEE, INC

5820 WESTOWN PARKWAY

WEST DES MOINES, IA 50266

SATISFACTION GUARANTEED

OR PURCHASE PRICE REFUNDED

FOR INFORMATION CALL

1-800-288-8343

### **Principal Display Panel**

HyVee

Compare to the active  
ingredients in Listerine

Oral Rinse

Antiseptic

Mouth rinse

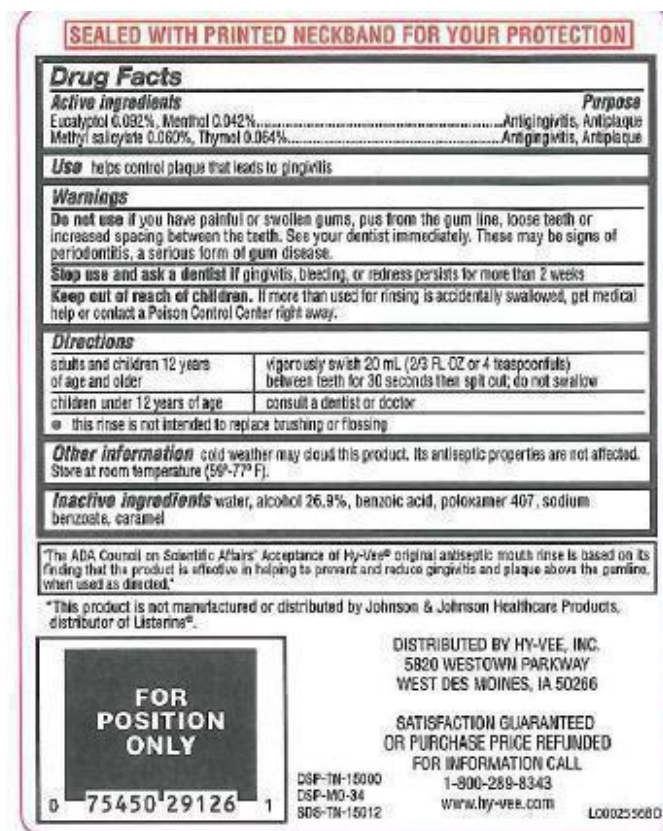
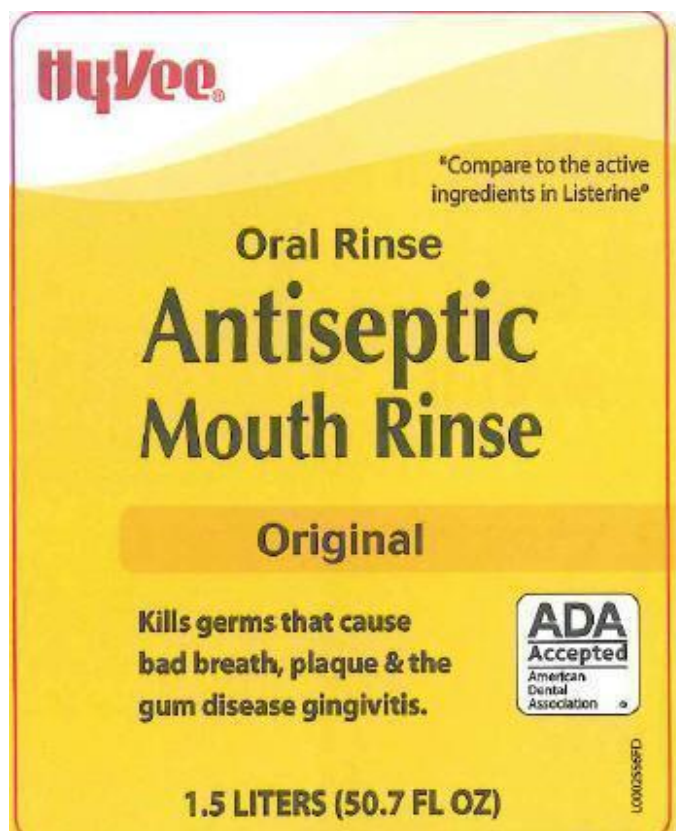
Original

ADA

Accepted

American

Dental  
 Association  
 Kills germs that cause  
 bad breath, plaque & the  
 gum disease gingivitis  
 1.5 LITERS (50.7 FL OZ)



## ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42507-318
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	0.6 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)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42507-318-86	1000 mL in 1 BOTTLE, PLASTIC		
2	NDC:42507-318-12	1500 mL in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	08/15/1990	

**Labeler** - Hy-Vee Inc (006925671)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture(42507-318)

Revised: 9/2012

Hy-Vee Inc