

**ADVANCED ANTISEPTIC - eucalyptol 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**

**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** could 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, flavoring, PEG-40 hydrogenated castor oil, poloxamer 407,

benzoic acid, zinc chloride, sucralose and/or sodium saccharin, sodium benzoate, yellow 6, red 40

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

DSP-TN-15000

DSP-MO-34

SDS-TN-15012

DISTRIBUTED BY

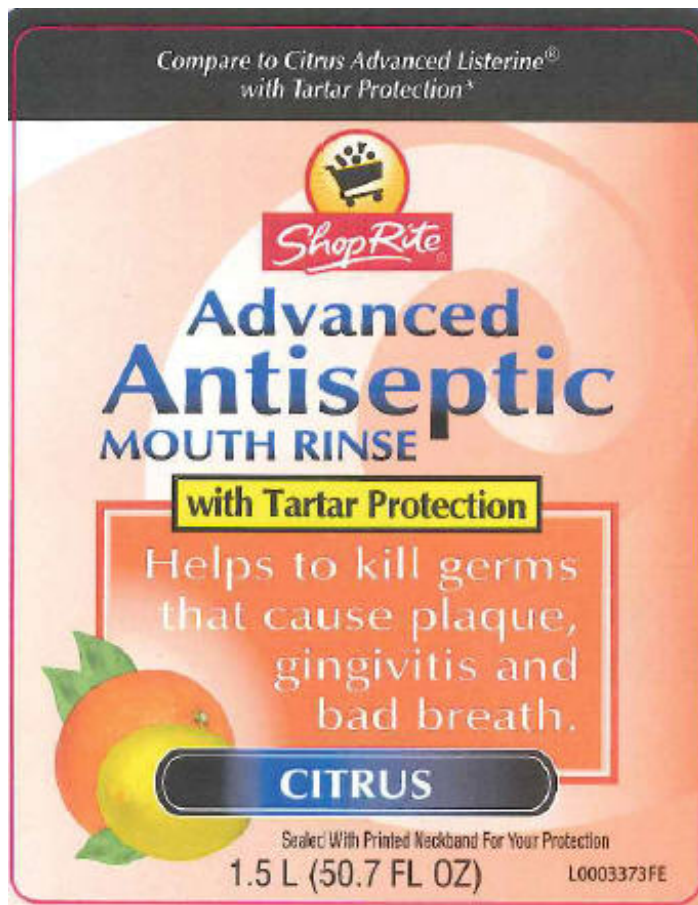
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Helps to kill germs

that cause plaque,

gingivitis and

bad breath

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1.5 L (50.7 FL OZ)



## ADVANCED ANTISEPTIC

eucalyptol mouthwash

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41190-210
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)	EUCALYPTOL	.042 mL in 100 L
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	.042 mL in 100 L
METHYL SALICYLATE (UNII: LAV5U5022Y) (METHYL SALICYLATE - UNII:LAV5U5022Y)	METHYL SALICYLATE	.060 mL in 100 L
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	.064 mL in 100 L

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
SORBITOL (UNII: 506T60A25R)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	

<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>ZINC CHLORIDE</b> (UNII: 86Q357L16B)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41190-210-86	1 L in 1 BOTTLE, PLASTIC		
2	NDC:41190-210-12	1.5 L in 1 BOTTLE, PLASTIC		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/24/2010	

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

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

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Vi-Jon		790752542	manufacture