

ANTISEPTIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash
WinCo Foods, LLC

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 072

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.030%

Thymol 0.064%

purpose

antigingivitis, antiplaque

Use

helps 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

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. It 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, sodium saccharin, sodium citrate, D&C yellow no. 10, FD&C green no.3

Questions?

Or to report an adverse even call 800-824-1706

Monday - Friday 9am -4pm MST

ADA Council Statement

"The ADA Council on Scientific Affairs" Acceptance of WinCo Foods Spring Mint Antiseptic Mouth Rinse is based on its finding that the product is

effective in helping to prevent and reduct 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 Freshburst LISTERINE

Antiseptic Mouthwash.

Adverse reactions

DISTRIBUTED BY:WINCO FOODS, LLC BOISE, ID 83704

Comments & Questions?

800-824-1706 www.wincofoods.com

072.001/072AL

principal display package

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTIO

Compare to the active ingredients in Freshburst LISTERINE Antiseptic Mouthwash

WinCo

FOODS

ANTISEPTIC

MOUTH RINSE

ANTINGIVITIS/ANTIPLAQUE MOUTH RINSE

Kills Germs That Cause Bad Breath, Plaque and Gingivitis Gum Disease

For Better Oral Hygiene and Fresher Breath

ADA

Accepted

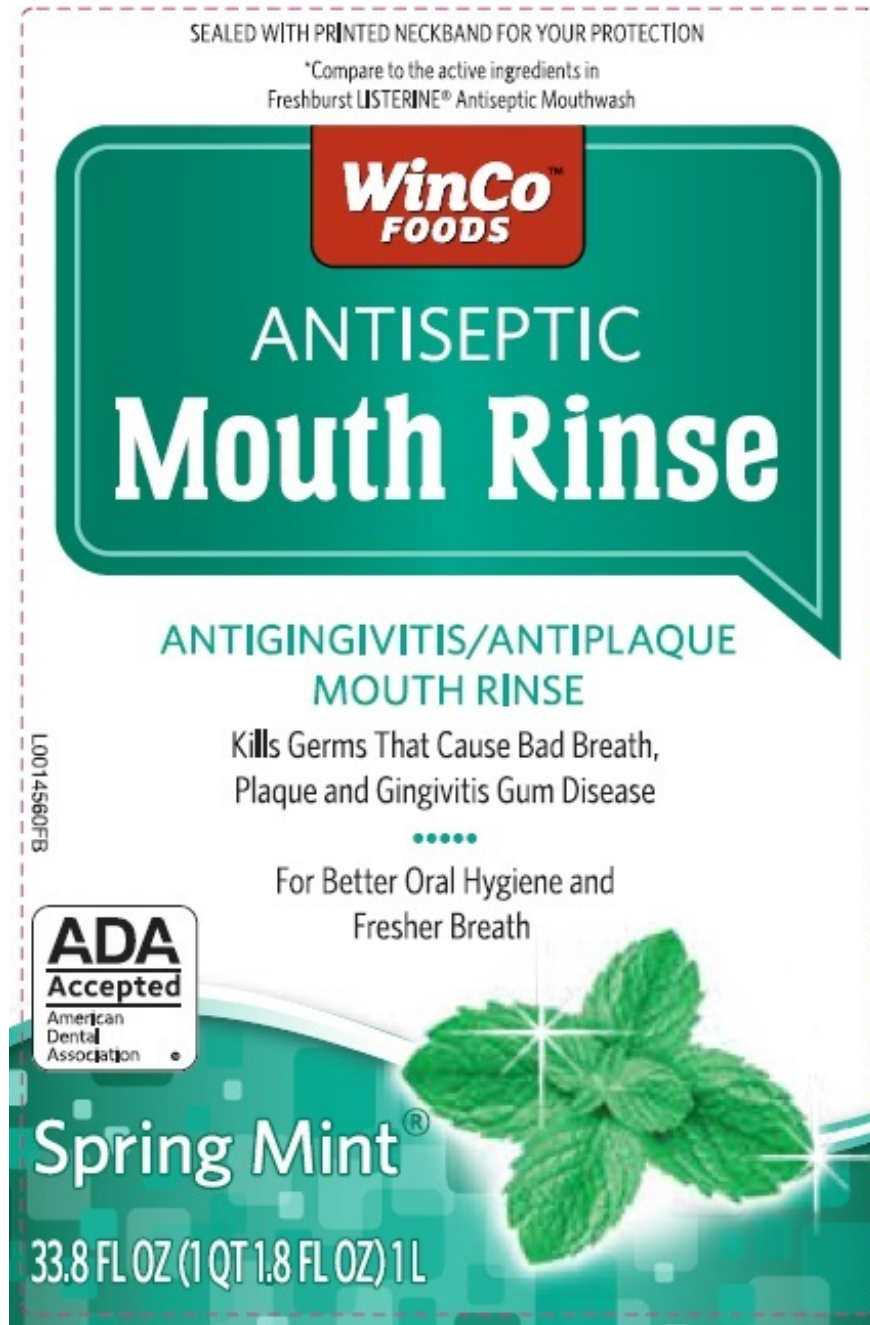
American

Dental

Association

Spring Mint

33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



ANTISEPTIC

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67091-102

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 CITRATE (UNII: 1Q73Q2JULR)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67091-102-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/03/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/03/2014	

Labeler - WinCo Foods, LLC (056098817)

Registrant - Vi-Jon (790752542)