# ANTISPETIC- 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**

#### 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 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. 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, sodium saccharin, sodium benzoate, FD&C green no.3

#### **Questions**

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

Monday - Friday 9am - 4pm MST

### ADA Council statement

"The ADA Council on Scientific Affairs' Acceptance of WinCo Foods Blue Mint Antiseptic Mouth Rinse is based on its finding that the product is effective in helping to prevent and reduce gingivitis and plaque above the gumline, when used as directed."

#### Disclaimer

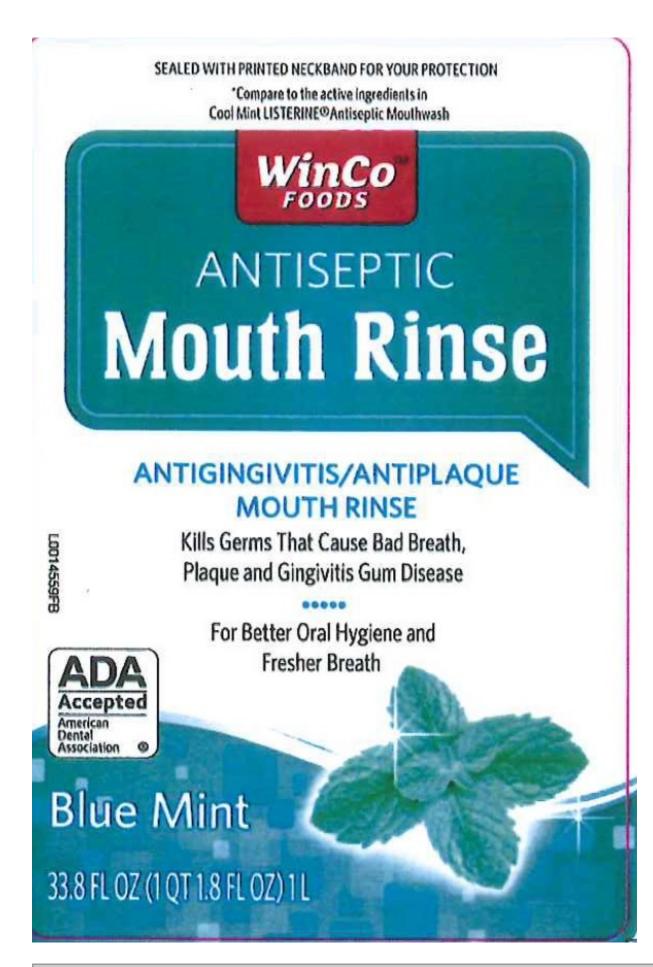
This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributor of Cool Mint LISTERINE Antiseptic Mouthwash.

#### Adverse Reactions

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

664.002/664AT

principal display panel SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION Compare to the active ingredients in Cool Mist LISTERINE Antiseptic Mouthwash WinCo FOODS ANTISEPTIC MOUTH RINSE ANTIGINGIVITIS/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 Blue Mint 33.8 FL OZ (1 QT 1.8 FL OZ) 1 L



Product Inform	ation					
Product T ype		HUMAN OTC DRUG	Item Code	(Source)	NDC:6	7091-103
Route of Administ	ration	ORAL				
Active Ingredie	nt/Active Mo	iety				
Ingredient Name Basis of Str						Strength
EUCALYPTOL (UNII: RV6J6604TK) (EUCALYPTOL - UNII:RV6J6604TK)					EUCALYPTOL	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) MENTHOL						0.42 mg in 1 mI
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) METHYL SALIC						0.60 mg in 1 ml
<b>THYMOL</b> (UNII: 3J50 XA376E) (THYMOL - UNII:3J50 XA376E) THYMOL						0.64 mg in 1 mI
Inactive Ingred	ients					
		Ingredient Name			:	Strength
WATER (UNII: 059Q	F0KO0R)					
ALCOHOL (UNII: 31	K9958V90M)					
SORBITOL (UNII: 5	06T60A25R)					
POLOXAMER 407	UNII: TUF2IVW3N	/12)				
BENZOIC ACID (UN	III: 8 SKN0 B0 MIM					
SACCHARIN SODIU	M (UNII: SB8ZU)	(40 TY)				
SODIUM BENZOAT	<b>E (UNII: OJ245FE</b>	5EU)				
FD&C GREEN NO.	G (UNII: 3P3ONR6	O1S)				
Packaging						
# Item Code		Package Description		Marketing Start Date	t N	larketing End Date
$\begin{array}{c} 1 \\ 33 \end{array}^{\text{NDC:67091-103-}}$	000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product					
Marketing In						
	ory Applica	tion Number or Monograp	h Citation Ma	arketing Start Date	Marl	keting End Dat
Marketing Categ		5 1		19/2014		U

Labeler - WinCo Foods, LLC (056098817)

## Registrant - Vi-Jon (790752542)

Establishment							
Name	Address	ID/FEI	<b>Business Operations</b>				
Vi-Jo n		790752542	manufacture(67091-103)				