ANTISPETIC- eucalyptol, menthol, methyl salicylate, thymol mouthwash Topco

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.

Dye-Free Antiseptic Mint Mouthrinse 567.000/567AA

Active ingredients

Eucalyptol 0.092%

Menthol 0.042%

Methyl salicylate 0.060%

Thymol 0.064%

Purpose

Antigingivitis, Antiplaque

Use

help 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, poloxamer 407, benzoic acid, sodium saccharin, sodium benzoate, flavor

Questions

Call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES, LLC

ELK GROVE VILLAGE, IL 60007

TOPCO VIJA1121

QUESTIONS? 1-888-423-0139

topcare@topco.com

www.topcarebrand.com

Scan here for mroe information or call 1-888-423-0139

TEP

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION

Claims

QUALITY GUARANTEED

This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

Principal display panel

TopCare

everyday

DYE FREE

Antiseptic

Mouthwash

ANTIGINGIVITIS/ANTIPLAQUE

REFRESHING MINT

- Kills 99% of germs commonly associated with gingivitis
- Freshens breath
- With essential oils
- Sugar free

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



Antiseptic Mouthwash

ANTIGINGIVITIS / ANTIPLAQUE

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Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76162-567

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: 85KN0B0MIM)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		

l	Packaging				
	#	# Item Code Package Description		Marketing Start Date	Marketing End Date
		NDC:76162- 567-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/20/2021	

Marketing Information			
Marketing Application Number or Monograp Category Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part356	12/20/2021	

Labeler - Topco (006935977)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(76162-567)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(76162-567)

Revised: 7/2023 Topco