# ANTISEPTIC MOUTH RINSE- eucalyptol, menthol, methyol salicylate, thymol mouthwash TOPCO ASSOCIATES, 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.

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# Spring Mint Antiseptic Mouthrinse 072.003/072AN

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#### **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 citrate, D&C yellow no. 10, FD&C green no. 3

#### Questions?

Call 1-888-423-0139

#### Adverse reaction

\*This product is not manufactured or distributed by Johnson & Johnson Healthcare Products, distributer of FreshBurst Listerine Antiseptic Mouthwash.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

OUESTIONS? 1-888-423-0139

topcare@topco.com www.topcarebrand.com

The Top Care product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

#### principal display panel

COMPARE TO LISTERINE\*

TopCare

everyday

**Antiseptic** 

Mouthwash

ANTIGINGIVITIS/ANTIPLAQUE

#### **SPRING MINT**

- For better oral hygiene & fresher breath
- Kills germs that cause bad breath, plaque & the gum disease gingivitis

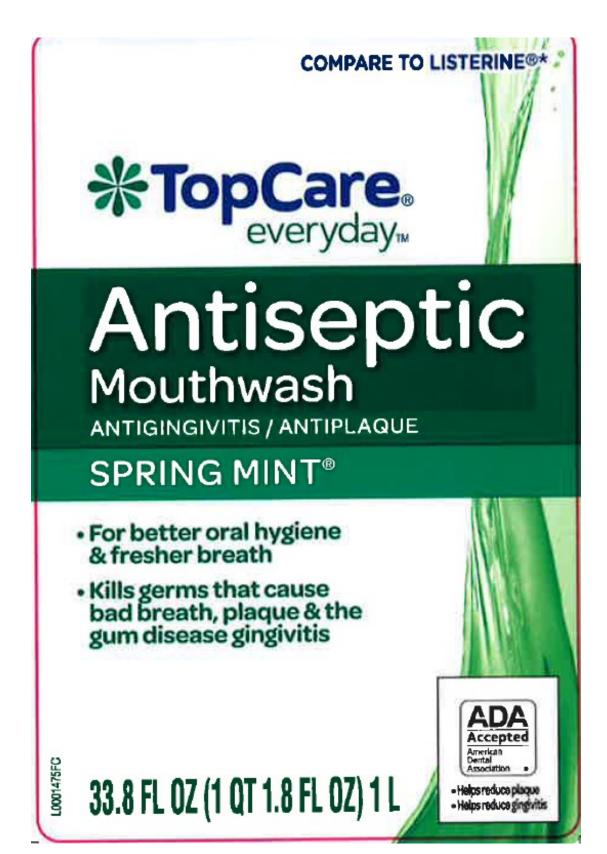
### ADA

# Accepted

American Dental Association

- Helps reduce plaque
- Helps reduce gingivitis

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



#### ANTISEPTIC MOUTH RINSE

eucalyptol, menthol, methyol salicylate, thymol mouthwash

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-072
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)		
POLOXAMER 407 (UNII: TUF2IVW3M2)		
BENZOIC ACID (UNII: 85KN0B0MIM)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
SODIUM CITRATE (UNII: 1Q73Q2JULR)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800- 072-86	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/1995	
2	NDC:36800- 072-12	1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/1995	
3	NDC:36800- 072-77	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/1995	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/07/1995	

# Labeler - TOPCO ASSOCIATES, LLC (006935977)

# Registrant - Vi-Jon, LLC (790752542)

## **Establishment**

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(36800-072)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(36800-072)

Revised: 2/2023 TOPCO ASSOCIATES, LLC