# SHOPKO BLUE MINT- eucalyptol, menthol, methyl salicylate, thymol mouthwash Apollo Health and Beauty Care Inc.

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

Antiplaque/Antigingivitis

# Uses

helps reduce plaque that leads to

- gingivitis
- bleeding gums

# Warnings

Stop use and ask a dentist if

- gingivitis, bleeding, or redness persists for more than 2 weeks
- you have painful or swollen gums, pus from the gum line, loose teeth, or increasing spacing between the teeth. These may be signs or symptoms of periodontitis, a serious form of gum disease.

# Keep out of reach of children under 6 years of age.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center immediately.

# Directions

- Adults and children 12 years of age and older: vigorously swish 20 milliliters of rinse between your eth twice a day for 30 seconds and then spit out. Do not swallow the rinse.
- children 6 years to under 12 years of age: supervise use
- children under 6 years of age: do not use

# Other information

- this rinse is not intended to replace brushing or flossing.
- store at room temperature. Cold weather may cloud this product, Its antiseptic properties are not affected.

# **Inactive ingredients**

Water (Aqua), Alcohol (21.6%), Sorbitol, Flavor, Poloxamer 407, Benzoic Acid, Sodium Saccharin, Sodium Benzoate, Green 3 (CI 42053).

#### **Questions or comments?**

#### Label copy



#### SHOPKO BLUE MINT

\_

eucalyptol, menthol, methyl salicylate, thymol mouthwash

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63148-000			
Route of Administration	ORAL					

Active Ingredient/Active Molety					
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: 8 SKN0 B0 MIM)			
SACCHARIN SO DIUM (UNII: SB8ZUX40TY)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)			

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
		1500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/07/2018				
	50	Tioudet					
	00	riodact					
Μ	arketing In Aarketing Categ	formation	Marketing Start Date	Marketing End Dat			

Labeler - Apollo Health and Beauty Care Inc. (201901209)

**Registrant** - Apollo Health and Beauty Care Inc. (201901209)

Establishment						
Name	Address	ID/FEI	<b>Business Operations</b>			
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-000)			

Revised: 6/2018

Apollo Health and Beauty Care Inc.