P.O.V. SUGARFREE- 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 doctor 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 periodonitis, a serious form of gum disease.

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

If more than used for rinsing is accidently 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 teeth 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%), Flavor, Poloxamer 407, Benzoic Acid, Sodium Saccharin, Sucralose, Sodium Benzoate, Green 3 (CI 42053).

Questions or comments?

1-866-695-3030

Label Copy

P.O.V. SUGARFREE

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Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63148-565
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: 8SKN0B0MIM)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63148-565-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/28/2018	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
Apollo Health and Beauty Care Inc.		201901209	manufacture(63148-565)

Revised: 3/2018 Apollo Health and Beauty Care Inc.