QUALITY CHOICE AMBER- eucalyptol, menthol, methyl salicylate, thymol liquid
CHAIN DRUG MARKETING ASSOCIATION 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

To help reduce and prevent plaque and gingivitis

Warnings

Do not use for children under 12 years of age.

Keep out of reach of children

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Directions

- Rinse full strength for 30 seconds with 20 mL (2/3 fluid ounce or 4 teaspoonfuls) morning and night.
- Do not swallow.

Other information

- Store at room temperature.
- Cold weather may cloud this product. Its antiseptic properties are not affected.

Inactive ingredients

Water (Aqua), Alcohol (26.9%), Benzoic Acid, Poloxamer 407, Sodium Benzoate, Caramel.

Questions or comments?

1-248-449-9300

Label Copy

QUALITY CHOICE AMBER

eucalyptol, menthol, methyl salicylate, thymol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63868-556
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)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging				
#	Item Code	Package Description	Marketing Start	Marketing End

#	Item Code	Package Description	Date	Date
1	NDC:63868-556-33	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	09/13/2015	

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(63868-556)

Revised: 9/2015 CHAIN DRUG MARKETING ASSOCIATION INC