MARCS ORIGINAL- eucalyptol, menthol, methyl salicylate, thymol liquid APOLLO HEALTH AND BEAUTY CARE

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 IMMEDIATELY (1-800-222-1222)

DIRECTIONS

RINSE FULL STRENGTH FOR 30 SECONDS WITH 20 ML (2/3 FLUID OUNCE OR 4 TEASPOONFULS) MORNING AND NIGHT. DO NOT SWALLOW

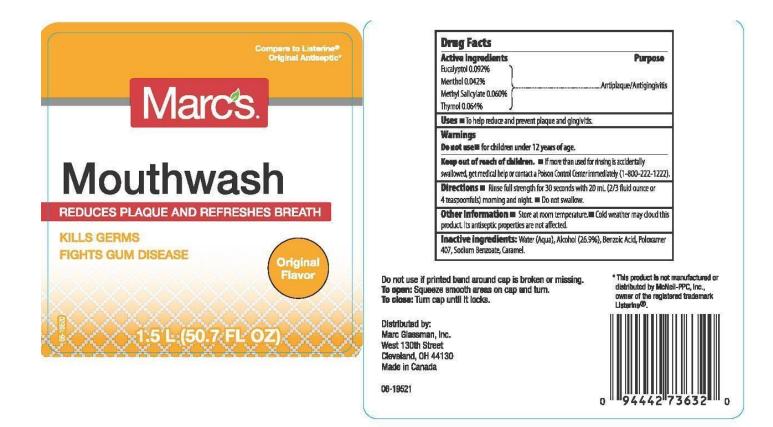
OTHER INFORMATION

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

LABEL COPY



MARCS ORIGINAL eucalyptol, menthol, methyl salicylate, thymol liquid Product Information Product Type HUMAN OTC DRUG Route of Administration ORAL

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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:0414PZ4LPZ)	METHYL SALICYLATE	0.6 mg in 1 mL
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.64 mg in 1 mL

Ingredient Name	Strength
	Strength
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
CARAMEL (UNII: T9D99G2B1R)	

Packaging					
# Item Code	Package Description	Marketing	Start Date	Marketing End Date	
1 NDC:63148-556-51	1500 mL in 1 BOTTLE, PLASTIC				
Marketing Infor	mation				
Marketing Infor Marketing Category	mation Application Number or Monograph	Citation Ma	arketing Start Date	Marketing End Date	
Marketing Infor Marketing Category OTC monograph not final			arketing Start Date 13/2014	Marketing End Date	

Labeler - APOLLO HEALTH AND BEAUTY CARE (201901209)

Registrant - APOLLO HEALTH AND BEAUTY CARE (201901209)

Establishment						
Name	Address	ID/FEI	Business Operations			
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture(63148-556)			

Revised: 2/2014

APOLLO HEALTH AND BEAUTY CARE