

**MAYBELLINE NEW YORK BABY LIPS DR RESCUE MENTHOL EXTERNAL
ANALGESIC MEDICATED BALM- menthol lipstick
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Menthol 0.5%

Purpose

External analgesic

Use

- for the temporary relief of pain associated with fever blisters and cold sores

Warnings

For external use only

When using this product

do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- for adult use only: apply to affected area not more than 3 to 4 times daily

polybutene, octyldodecanol, petrolatum, isopropyl myristate, polyethylene, ozokerite, diisostearyl malate, butyrospermum parkii (shea) butter, euphorbia cerifera (candelilla) wax, VP/hexadecene copolymer, eucalyptus globulus leaf oil, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, tocopherol, tocopheryl acetate, alumina, limonene, aluminum hydroxide, synthetic fluorphlogopite, calcium sodium borosilicate, calcium aluminum borosilicate, silica, honey, centella asiatica extract, dimethicone, tin oxide,

BHT, citric acid, titanium dioxide, iron oxides, red 22 lake, red 7, red 28 lake, mica, yellow 5 lake, yellow 6 lake, blue 1 lake, carmine

Questions or comments?

1-800-322-2036 Monday - Friday (9 a.m. - 5 p.m. EST)



C1 - Internal use

MAYBELLINE NEW YORK BABY LIPS DR RESCUE MENTHOL

EXTERNAL ANALGESIC MEDICATED BALM

menthol lipstick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-494
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		MENTHOL	5 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
OCTYLDODECANOL (UNII: 461N1O614Y)			
PETROLATUM (UNII: 4T6H12BN9U)			
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
DIISOSTEARYL MALATE (UNII: QBS8A3XZ GQ)			
SHEA BUTTER (UNII: K49155WL9Y)			
CANDELILLA WAX (UNII: WL0328HX19)			
VINYLPIRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)			
TOCOPHEROL (UNII: R0ZB2556P8)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
ALUMINUM OXIDE (UNII: LMI26O6933)			
LIMONENE, (+)- (UNII: GFD7C86Q1W)			
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
CALCIUM SODIUM BOROSILICATE (UNII: 4MM76N4VMY)			
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
HONEY (UNII: Y9H1V576FH)			
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
STANNIC OXIDE (UNII: KM7N50LOS6)			
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
FERRIC OXIDE RED (UNII: 1K09F3G675)			
D&C RED NO. 7 (UNII: ECW0LZ41X8)			
MICA (UNII: V8A1AW0880)			
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)			
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-494-01	1 in 1 BLISTER PACK	06/01/2016	
1		4.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	06/01/2016	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'OREAL USA PRODUCTS, INC		624244349	manufacture(49967-494)

Revised: 6/2024

L'Oreal USA Products Inc