

**EIGHT HOUR CREAM LIP PROTECTANT SHEER TINT SPF 15 BERRY- petrolatum stick
Elizabeth Arden, 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.

BL1472

DESCRIPTION

Moisturizes, softens and smooths lips. Provides antioxidant protection with vitamin E. SPF 15 protects against UV exposure. Provides a sheer wash of color in 6 translucent shades. Dermatologist, clinically and allergy tested.

INDICATIONS AND USAGE

To Use: Apply liberally as often as necessary.

WARNINGS

Warning: If condition worsens or does not improve within 7 days, consult a physician.

OTC - ACTIVE INGREDIENT

Active Ingredients: Petrolatum, 30.2% w/w, Padimate O, 8.0% w/w, Oxybenzone, 3.0% w/w.

INACTIVE INGREDIENT

Other Ingredients: Ozokerite, Ricinus Communis (Castor) Seed Oil, Glyceryl Rosinate, Cetyl Lactate, Lanolin Oil, Myristyl Lactate, Cetyl Acetate, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera/Cire De Candelilla, Copernicia Cerifera (Carnauba) Wax/Cer Carnauba/Cire De Carnauba, Beeswax/Cera Alba/Cire D'Abeille, Tocopherol, Acetylated Lanolin Alcohol, Methylstyrene/Vinyltoluene Copolymer, Microcrystalline Wax/Cera Microcristallina/Cire Microcristalline, BHT, Vegetable Oil/Olus/Huile Vegetale, Zea Mays (Corn) Oil, Citral Citronellol, Geraniol, Limonene, Linalool, Butylparaben, Propylparaben.

May Contain: Blue 1 Lake (CI 42090), Iron Oxides (CI 77491, CI 77499, CI 77492), Red 6 Lake (CI 15850), Red 7 Lake (CI 15850), Red 21 Lake (CI 45380), Red 27 Lake (CI 45410), Titanium Dioxide (CI 77891), Yellow 5 Lake (CI 19140), Yellow 6 Lake (CI15985).

DOSAGE & ADMINISTRATION

Apply to lips.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

SPF 15 protects against UV exposure.

OTC - WHEN USING

Note condition.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Elizabeth Arden

Eight Hour Cream Lip Protectant Stick

Sheer Tint SPF 15

NET WT. .13 OZ. 3.7 g

ACTIVE INGREDIENTS: PETROLATUM, 30.2% W/W, PADIMATE O, 8.0% W/W, OXYBENZONE, 3.0% W/W
OTHER INGREDIENTS: RICINUS COMMUNIS (CASTOR) SEED OIL, OZOKERITE, GLYCERYL ROSINATE, CETYL LACTATE,
LANOLIN, MYRISTYL LACTATE, CETYL ACETATE, EUPHORBIA CERIFERA (CANDELLA) WAX, COPERNICIA CERIFERA
(CARNAUBA) WAX, BEESWAX, TOCOPHEROL, ACETYLATED LANOLIN ALCOHOL, METHYLSTYRENE/VINYLTOLUENE
COPOLYMER, MICROCRYSTALLINE WAX, BHT,
VEGETABLE OIL, ZEA MAYS (CORN) OIL, FRAGRANCE,
CITRAL, CITRONELLOL, GERANIOL, LIMONENE,
LINALOOL, BUTYL PARABEN, PROPYL PARABEN.
MAY CONTAIN: BLUE 1 LAKE, IRON OXIDES, RED 6
LAKE, RED 7 LAKE, RED 21 LAKE, RED 27 LAKE,
TITANIUM DIOXIDE, YELLOW 5 LAKE, YELLOW 6 LAKE.



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New York, NY 10003
Made in U.S.A. No. 0704-0
ElizabethArden.com



This carton is recyclable.

Eight Hour Cream
 Lip Protectant Stick
 Sheer Tint SPF 15
 NET WT. .13 OZ.
 3.7 g ↷

ACTIVE
 INGREDIENTS:
 PADIMATE O,
 8.0% W/W
 OXYBENZONE,
 3.0% W/W
 PETROLATUM,
 30.2% W/W

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 New York, NY 10003
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EIGHT HOUR CREAM LIP PROTECTANT SHEER TINT SPF 15 BERRY

petrolatum stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1472
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1.117 g in 3.7 g
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	0.296 g in 3.7 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.111 g in 3.7 g

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
MYRISTYL LACTATE (UNII: 1D822OC34X)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLPARABEN (UNII: 3QPIIU3FV8)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
CORN OIL (UNII: 8470G57WFM)	

Product Characteristics

Color	RED (Berry)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1472-1	1 in 1 BOX		
1	NDC:67938-1472-2	3.7 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/28/2006	

Labeler - Elizabeth Arden, Inc (849222187)