

## **EIGHT HOUR CREAM LIP PROTECTANT SPF 15- 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.*

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**BL0774**

### **DESCRIPTION**

An all weather treatment stick for softer, smoother lips. Sunscreen ingredients (SPF 15) guard against the damaging effects of sun exposure. Dermatologist, clinically and allergy tested.

### **INDICATIONS AND USAGE**

Apply to lips.

### **WARNINGS**

Warnings: Discontinue use if signs of irritation or rash appear and see a doctor. Keep out of reach of children.

### **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: Ricinus Communis (Castor) Seed Oil, Ozokerite, Glyceryl Rosinate, Cetyl Lactate, Myristyl Lactate, Lanolin Oil, Cetyl Acetate, Euphorbia Cerifera (Candelilla) Wax/Candelilla Cera/Cire de Candelilla, Copernicia Cerifera (Carnauba) Wax/Cera 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/Huille Vegetale, Zea Mays (Corn) Oil, Parfum/Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Butylparaben, Propylparaben, Iron Oxides.

### **DOSAGE & ADMINISTRATION**

Apply to lips.

### **OTC - KEEP OUT OF REACH OF CHILDREN**

Keep out of reach of children.

### **OTC - PURPOSE**

Protects skin. Provides SPF 15 sun protection.

### **OTC - WHEN USING**

Discontinue use if signs of irritation or rash appear.

# Elizabeth Arden

Eight Hour Cream Lip Protectant Stick

SPF 15

NET WT. .13 OZ. 3.7 g

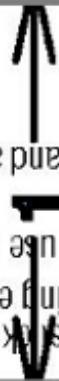
ACTIVE INGREDIENTS: PETROLATUM 30.2 % W/W, PADIMATE A 8.0 % W/W, OXYBENZONE 3.0 % W/W.  
OTHER INGREDIENTS: RICINUS COMMUNIS (CASTOR) SEED OIL, OZOKERITE, GLYCERYL ROSINATE, CETYL LACTATE,  
LANOLIN, MYRISTYL LACTATE, CETYL ACETATE, EUPHORBIA CERIFERA (CANDELLILLA) WAX, COPERNICIA CERIFERA  
(CARNAUBA) WAX, BEESWAX, TOCOPHEROL, ACETYLATED LANOLIN ALCOHOL, METHYLSTYRENE/VINYLTOLUENE  
COPOLYMER, MICROCRYSTALLINE WAX, BHT, VEGETABLE OIL,  
ZEA MAYS (CORN) OIL, FRAGRANCE, CITRAL, CITRONELLOL,  
GERANIOL, LIMONENE, LINALOOL, BUTYLPARABEN,  
PROPYLPARABEN, IRON OXIDES.

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Made in U.S.A. No. 4253000  
ElizabethArden.com



This carton is recyclable.

An all weather treatment stick for softer, smoother lips. Sunscreen ingredients (SPF 15)  
guard against the damaging effects of sun exposure.  
**Warnings:** Discontinue use if signs of irritation or rash appear and see a doctor. Keep  
out of reach of children.  
Dermatologist, clinically and allergy tested.



Eight Hour Cream  
Lip Protectant Stick  
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 10105  
Made in U.S.A.  
No. 4253-000

**EIGHT HOUR CREAM LIP PROTECTANT SPF 15**

petrolatum stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67938-0774
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PETROLATUM</b> (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1.12 g in 3.7 g
<b>PADIMATE O</b> (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	0.296 g in 3.7 g
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.111 g in 3.7 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>MYRISTYL LACTATE</b> (UNII: 1D822OC34X)	
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>BUTYLPARABEN</b> (UNII: 3QP1I03FV8)	
<b>CORN OIL</b> (UNII: 8470G57WFM)	
<b>ALPHA-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0774-1	1 in 1 BOX		
1	NDC:67938-0774-2	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	05/31/2006	

**Labeler** - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc