

**EA EIGHT HOUR SKIN PROTECTANT- petrolatum emulsion
REVLON**

ELIZABETH ARDEN EIGHT HOUR CREAM SKIN PROTECTANT

ACTIVE INGREDIENTS

Petrolatum 56.8%..... Skin Protectant

OTHER INGREDIENTS

LANOLIN, MINERAL OIL/PARAFFINUM LIQUIDUM/HUILE MINERALE, CAPRYLYL GLYCOL, GLYCINE SOJA (SOYBEAN) OIL, PARFUM/FRAGRANCE, RICINUS COMMUNIS (CASTOR) SEED OIL, SALICYLIC ACID, TOCOPHEROL, ZEA MAYS (CORN) OIL, BHT, CITRAL, CITRONELLOL, GERANIOL, LIMONENE, LINALOOL, PHENOXYETHANOL, IRON OXIDES (CI 77491, CI 77492).

USES

Treats symptoms of:

- chapping
- peeling or flaking due to minor burns
- sunburn
- windburn
- scrapes
- abrasions
- cracked lips

WARNINGS

Warnings

- For external use only

When using this product

- Avoid contact with eyes
- Do not apply over puncture wounds, infections or lacerations

Stop using and ask a doctor if

- Symptoms persist more than 7 days

DIRECTIONS

- Apply liberally as often as necessary
 - Apply liberally as often as necessary

- For external use only

Uses

Treats symptoms of:

- chapping
- peeling or flaking due to minor burns
- sunburn
- windburn
- scrapes
- abrasions
- cracked lips

NA

Skin Protectant

CARTON ART

CARTON ART

 <p>NET WT. 1.7 OZ. 50 g</p>		<p>Elizabeth Arden NEW YORK</p> <p>THE ORIGINAL</p> <p>Eight Hour® Cream Skin Protectant</p> <p>NET WT. 1.7 OZ. 50 g</p>	<p>This legendary skincare classic works wonders to moisturize and protect anytime, anyway you choose. Shape brows, revitalize shine, soothe dry hands and smooth cuticles and nails.</p> <p>Drug Facts</p> <table border="1"> <tr> <td><i>Active Ingredient</i></td> <td><i>Purpose</i></td> </tr> <tr> <td>Petrolatum 56.8%</td> <td>Skin Protectant</td> </tr> </table> <p><i>Uses</i> Treats symptoms of:</p> <ul style="list-style-type: none"> chapping peeling or flaking due to minor burns sunburn windburn scrapes abrasions cracked lips <p><i>Warnings</i></p> <ul style="list-style-type: none"> For external use only <p>When using this product</p> <ul style="list-style-type: none"> Avoid contact with eyes Do not apply over puncture wounds, infections or lacerations <p>Stop using and ask a doctor if</p> <ul style="list-style-type: none"> Symptoms persist more than 7 days <p><i>Directions</i></p> <ul style="list-style-type: none"> Apply liberally as often as necessary <p><i>Inactive Ingredients</i></p> <p>LANOLIN, MINERAL OIL/PARAFFINUM LIQUIDUM/HUILE MINERALE, CAPRYLYL GLYCOL, GLYCINE SOJA (SOYBEAN) OIL, PARFUM/FRAGRANCE, FICUS COMMUNIS (CASTOR) SEED OIL, SALICYLIC ACID, TOCOPHEROL, ZEA MAYS (CORN) OIL, BHT, CITRAL, CITRONELLOL, GERANIOL, LIMONENE, LINALOOL, PHENOXYETHANOL, IRON OXIDES (CI 77491, CI 77492).</p> <p>Distributed in U.S.A. by ©Elizabeth Arden, Inc. New York, NY 10003 elizabetharden.com</p> <p>Made in U.S.A.</p> <p>No. EIGN0090</p> <p>This carton is recyclable.</p> 	<i>Active Ingredient</i>	<i>Purpose</i>	Petrolatum 56.8%	Skin Protectant
<i>Active Ingredient</i>	<i>Purpose</i>						
Petrolatum 56.8%	Skin Protectant						

EA EIGHT HOUR SKIN PROTECTANT

petrolatum emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-672
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	56.8 mg in 1 g
---	------------	----------------

Inactive Ingredients

Ingredient Name	Strength
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
LANOLIN (UNII: 7EV65EAW6H)	
MINERAL OIL (UNII: T5L8T28FGP)	
SOYBEAN OIL (UNII: 241ATL177A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GERANIOL (UNII: L837108USY)	
CORN OIL (UNII: 8470G57WFM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CASTOR OIL (UNII: D5340Y2I9G)	
CITRAL (UNII: T7EU009VPP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-672-17	50 g in 1 TUBE; Type 0: Not a Combination Product	02/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M016	02/16/2016	

Labeler - REVLOL (788820165)

Registrant - REVLOL (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
BEAUTYGE S.L.		472062523	manufacture(10967-672)