

**EIGHT HOUR NOURISHING LIP SPF 20- octinoxate, avobenzone emulsion
REVLON**

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.

**ELIZABETH ARDEN EIGHT HOUR CREAM NOURISHING LIP BALM BROAD
SPECTRUM SUNSCREEN SPF 20**

Active Ingredients

Active Ingredients Purpose

OCTINOXATE 4.0%.....Sunscreen
AVOBENZONE 3.0%.....Sunscreen

Inactive Ingredients

POLYBUTENE, MICROCRYSTALLINE WAX/CERA MICROCRISTALLINA/CIRE
MICROCRISTALLINE, PETROLATUM, RICINUS COMMUNIS (CASTOR) SEED OIL,
BUTYROSPERMUM PARKII (SHEA) BUTTER, NYLON-12, DIOCTYLDODECYL
DODECANEDIOATE, C12-15 ALKYL BENZOATE, GLYCERETH-26, BUTYLOCTYL
SALICYLATE, LANOLIN, ASTROCARYUM MURUMURU SEED BUTTER, BEESWAX/CERA
ALBA/CIRE D'ABEILLE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA
CARNAUBA/CIRE DE CARNAUBA, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL,
HONEY EXTRACT, HYDROGENATED CASTOR OIL, LINOLEIC ACID, LINOLENIC ACI,
NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT, RETINYL PALMITATE, TO
DCOPHEROL, TOCOPHERYL ACETATE, BHT, IRON OXIDES (CI 77491, CI 77492).

Uses

Uses

- Helps prevent sunburn
- If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

Warnings

- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions For Sunscreen Use

Directions For Sunscreen Use:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - at least every 2 hours
- Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - Wear long-sleeve shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor.

CARTON ART

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50 PERCENT SCALE



Inside

Outside
Panel 2

This panel is behind
the Front Panel →

<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away. <p>Directions For Sunscreen Use:</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure Reapply: <ul style="list-style-type: none"> at least every 2 hours Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeve shirts, pants, hats, and sunglasses Children under 6 months: Ask a doctor. <p>Inactive Ingredients</p> <p>POLYBUTENE, MICROCRYSTALLINE WAX/CERA, MICROCRYSTALLINE WAX/CERA, MICROCRYSTALLINE WAX/CERA, PETROLATUM, RICINUS COMMUNIS (CASTOR) SEED OIL, BUTYROSPERMUM PARKII (SHEA) BUTTER.</p>	<p>Drug Facts (continued)</p> <p>NYLON-12, DIOCTYLDODECYL DODECANEDIATE, C12-15 ALKYL BENZOATE, GLYCERETH-26, BUTYLOCTYL SALICYLATE, LANTANA, ASTROCARYUM MURUMURU SEED BUTTER, BEESWAX/CERA ALBA/CIRE D'ABELLE, COPERNICIA CERIFERA (CARNAUBA) WAX/CERA, CARNAUBA/CIRE DE CARNAUBA, HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL, HONEY EXTRACT, HYDROGENATED CASTOR OIL, LINOLEIC ACID, LINOLENIC ACID, NASTURTIUM OFFICINALE FLOWER/LEAF EXTRACT, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, BHT, IRON OXIDES (CI 77491, CI 77492).</p> <p>Other Information</p> <ul style="list-style-type: none"> Protect this product from excessive heat and direct sun. <p>Questions or comments?</p> <ul style="list-style-type: none"> Call toll free 1-800-325-7337
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Panel 3
Panel 4
Panel 5

<p>Drug Facts (continued)</p> <p>Stop use and ask a doctor if rash occurs</p> <p>When using this product keep out of eyes. Flush with water to remove.</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p>	<p>Warnings</p> <p>Do not use on damaged or broken skin</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p>
<p>Drug Facts (continued)</p> <p>Active Ingredients</p> <p>OCTINOXATE 4.0%.....</p> <p>AVOBENZONE 3.0%.....</p>	<p>Drug Facts (continued)</p> <p>Uses</p> <ul style="list-style-type: none"> Helps prevent sunburn If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun

EIGHT HOUR NOURISHING LIP SPF 20

octinoxate, avobenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-671
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
CASTOR OIL (UNII: D5340Y2I9G)	
NYLON-12 (UNII: 446U8J075B)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ASTROCARYUM MURUMURU SEED BUTTER (UNII: 12V64UPU6R)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
LANOLIN (UNII: 7EV65EAW6H)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
SHEA BUTTER (UNII: K49155WL9Y)	
GLYCERETH-26 (UNII: NNE56F2N14)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LINOLEIC ACID (UNII: 9KJL21T0QJ)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HONEY (UNII: Y9H1V576FH)	
LINOLENIC ACID (UNII: 0RBV727H71)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PETROLATUM (UNII: 4T6H12BN9U)	
DIOCTYLDODECYL DODECANEDIOATE (UNII: 7QDB5EE79Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10967-671-61	14.2 g in 1 TUBE, WTH APPLICATOR; Type 0: Not a Combination Product	10/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/21/2020	

Labeler - REVLON (788820165)

Registrant - REVLON (788820165)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab. INC.		080987545	manufacture(10967-671)

Revised: 2/2022

REVLON