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 AV0BENZONE 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

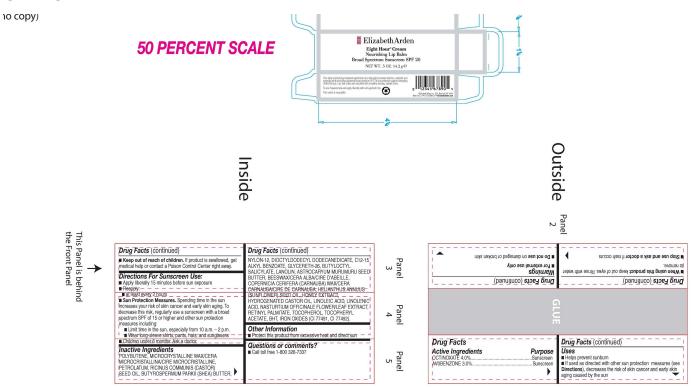
- For external use only
- Do not use on damaged or broken skin
- When using this product keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if rash occurs
- Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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.

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Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration Active Ingredient/Active Moiety Ingredient Name Basis of Strength

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 mg in 1 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	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)	
.ALPHATOCOPHEROL 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: EX43802MRT)	
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
	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)

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

Revised: 2/2022 REVLON