ELIZABETH ARDEN EIGHT HR PROTECTANT CLEAR- lip protectant lipstick REVLON CONSUMER PRODUCTS CORP

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 LIP PROTECTANT STICK SUNSCREEN SPF 15- CLEAR

ACTIVE INGREDIENTS

ACTIVE INGREDIENT PURPOSE PETROLATUM 31.0% SKIN PROTECTANT AVOBENZONE 2.0% SUNSCREEN OCTINOXATE 7.5% SUNSCREEN OXYBENZONE 3.0% SUNSCREEN

USES

- helps prevent sunburn
- Temporarily protects and helps relieve
- chapping
- peeling or flaking due to minor sunburn
- windburn
- cracked lips

Warnings

Skin Cancer/Skin Aging Alert: spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

- For external use only
- Do not use on damaged or broken skin
- Stop use and ask a doctor if rash occurs or if condition lasts more than 7 days.
- **Keep out of reach of children.If** product is swallowed get medical help or contact a Poison Control Center right away.

Directions

Directions

• Apply liberally as often as necessary

For Sunscreen Use:

• Apply liberally 15 minutes before sun exposure

- reapply:
- atleast every 2 hours
- children under 6 months: Ask a doctor.

Other Information

Other information

• Protect this product from excessive heat and direct sun

Inactive ingedients

Polybutene, Bis-Diglyceryl Polyacyladipate-2, Polyethylene, Diisostearyl Malate, Ozokerite, Lanolin, Octyldodecyl Neopentanoate, Synthetic Fluorphlogopite, Hydrogenated Polyisobutene, Cetyl PEG/PPG-10/1 Dimethicone, Mica, Polyglyceryl-4 Isostearate, Hexyl Laurate, Synthetic Wax, BHT, Butyrospermum Parkii (Shea) Butter, Cera Alba/Beeswax/Cire D'abeille, Cocos Nucifera (Coconut) Oil, Tocopheryl Acetate, Parfum (Fragrance), Citral, Citronellol, Geraniol, Limonene, Linalool, Benzoic Acid. **MAY CONTAIN/PEUT CONTENIR/PUEDE CONTENER (+/-):** [Iron Oxides (CI 77491), Iron Oxides (CI 77499), Red 33 Lake (CI 17200), Red 6 Lake (CI 15850), Red 7 Lake (CI 15850), Titanium Dioxide (CI 77891), Yellow 5 Lake (CI 19140).]

Questions or Comments?

- Call toll free 1-800-326-7337
- Monday to Friday, 10:00AM to 7:00PM EST

Skin protectant Directions

Apply liberally as often as necessary

Keep out of reach of children

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If product is swallowed, get medical help or contact poison control center right away.

Uses

- Helps prevent sunburn
- Temporarily protects and helps relieve
- Chapping
- Peeling or flaking due to minor sunburn
- Windburn
- Cracked lips

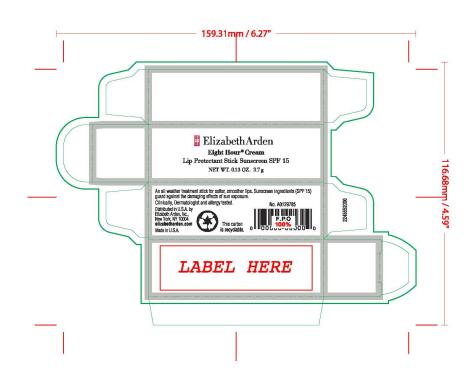
Directions and Usage

• Apply liberally as often as necessary

- For sunscreen use: apply liberally 15 minutes before sun exposure
- Reapply: atleast every 2 hours
- Children under 6 months: ask a doctor

Packaging Label

ELIZABETH ARDEN EIGHT HOUR CREAM LIP PROTECTANT STICK SUNSCREEN SPF 15 3.7 g - NORTH AMERICA FOLDING CARTON A0129785 159.31 mm W x 116.68 mm H







 RED DOOR ICON:

 PMS 200 C

 COPY / SYMBOLS / UPC PRINTS:

 BLACK

 GREEN RULES REPRESENT

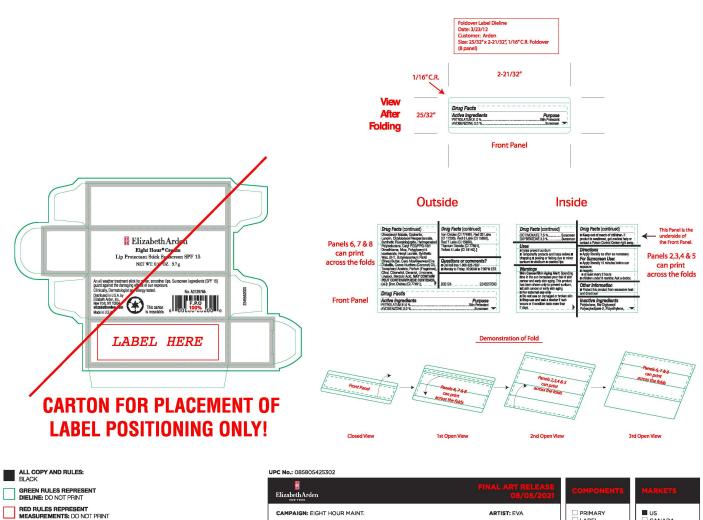
 DIELINE: DO NOT PRINT

RED RULES REPRESENT MEASUREMENTS: DO NOT PRINT

UPC No.: 085805425302

ElizabethArden	FINAL ART RELEASE 07/02/2021	COMPONENTS	MARKETS
	ARTIST: EVA CTANT STICK SUNSCREEN SPF 15 3.7 g LI.: N/A G No.: A0129785	PRIMARY LABEL CARD SET BOX CARTON INSERT HANGTAG	US CANADA NORTH AMERICA ASIA AUS EU LATAM
FILE NAME: 2245552000_EA_8Hr_Cream_L	ipPro_SPF15_CTN_07-02-2021_FIN	FILL = COMPONENTS INCLUDED IN SET	FILL = MARKET REGIONS

ELIZABETH ARDEN EIGHT HOUR CREAM LIP PROTECTANT STICK SUNSCREEN SPF 15 3.7 g - US ONSERT A0129785 2 21/32" W x 25/32" H



ElizabethArden		08/05/2021		
CAMPAIGN: EIGHT HOUR MAINT. JOB TITLE: EIGHT HOUR CREAM VARIANT: US COMPONENT: ONSERT COMPB: 2245557000 DIMENSIONS: 2 21/32" W x 25/32	LIP PROTECTANT STICK SUNSCREEN SP MLI.: B02124 FG No.: A0129785	ARTIST: EVA YF 15 3.7 g	PRIMARY LABEL CARD SET BOX ONSERT INSERT HANGTAG	US CANADA NORTH AMERICA ASIA AUS EU LATAM
FILE NAME: 2245557000_EA_8H	r_Cream_LipProtect_SPF15_ONSERT_NA	_08-05-2021_FIN	FILL = COMPONENTS INCLUDED IN SET	FILL = MARKET REGIONS

ELIZABETH ARDEN EIGHT HR PROTECTANT CLEAR

lip protectant lipstick

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10967-676	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	1.147 g in 3.7 g		
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.2775 g in 3.7 g		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	0.111 g in 3.7 g		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.074 g in 3.7 g		

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	Stiength
SYNTHETIC WAX (1200 MW) (UNII: Q3Z4BCH099)	
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)	
DIISOSTEARYL MALATE (UNII: OBS8A3XZGO)	
CERESIN (UNII: Q1LS2UJO3A)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)	
COCONUT OIL (UNII: Q9L0073W7L)	
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
LANOLIN (UNII: 7EV65EAW6H)	
BUTYROSPERMUM PARKII (SHEA) BUTTER UNSAPONIFIABLES (UNII: 0C9AC7D6XU)	
BENZOIC ACID (UNII: 85KN0B0MIM)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
Packaging	

#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:10967-676- 64	.0967-676- 3.7 g in 1 TUBE; Type 0: Not a Combination Product 02/01/2023			
Marketing Information					
	Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date	

02/01/2023

Labeler - REVLON CONSUMER PRODUCTS CORP (788820165)

Establishment			
Name	Address	ID/FEI	Business Operations
REVLON, INC		809725570	manufacture(10967-676)

OTC monograph final M016