

EIGHT HOUR CREAM SUN DEFENSE FOR FACE SPF 50 SUNSCREEN- zinc oxide lotion
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.

BC1094

DESCRIPTION

Provides powerful SPF 50 PA+++ protection to shield against UVA/UVB rays that can cause sunburn, surface skin cell damage and premature signs of aging. Lightweight, oil-free lotion helps protect your skin from sun exposure while hydrating for up to 8 hours. PABA free.

Uses: Helps prevent sunburn. Higher SPF gives more sunburn protection.

Sun Alert: Limiting sun exposure, wearing protective clothing and using sunscreens may reduce the risk of skin cancer and other harmful effects of the sun.

INDICATIONS AND USAGE

Directions: Apply liberally and evenly to face 30 minutes before sun exposure. Reapply as needed or after towel drying, swimming, or perspiring. Children under 6 months of age: ask a doctor.

WARNINGS

Warnings: For external use only. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

OTC - ACTIVE INGREDIENT

Active Ingredients: Zinc Oxide 11.62% w/w, Octinoxate 7.40% w/w, Octisalate 5.00% w/w.

INACTIVE INGREDIENT

Water/Aqua/Eau, C12-25 Alkyl Benzoate, Isodecyl Neopentanoate, Neopentyl Glycol Diheptanoate, Magnesium Aluminum Silicate, Glyceryl Stearate, PEG-100 Stearate, Caprylyl Glycol, Arachidyl Alcohol, Polyhydroxystearic Acid, Arachidyl Glucoside, Triethoxycaprylylsilane, Behenyl Alcohol, Xanthan Gum, BHT, Disodium EDTA, Parfum/Fragrance, Citral, Citronellol, Geraniol, Limonene, Linalool, Methylparaben, Phenoxyethanol, Sorbic Acid.

DOSAGE & ADMINISTRATION

Apply liberally and evenly to face.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

Helps prevent sunburn. Higher SPF gives more sunburn protection.

OTC - WHEN USING

Keep out of eyes.

Provides powerful SPF 50 PA+++ protection to shield against UVA/UVB rays that can cause sunburn, surface skin cell damage and premature signs of aging. Lightweight, oil-free lotion helps protect your skin from sun exposure while hydrating for up to 8 hours. PABA free.

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ACTIVE INGREDIENTS:
ZINC OXIDE 11.62% W/W,
OCTINOXATE 7.40% W/W,
OCTISALATE 5.00% W/W

OTHER INGREDIENTS: WATER/AQUA/EAU,
C12-15 ALKYL BENZOATE, ISODECYL
NEOPENTANOATE, NEOPENTYL GLYCOL
DIHEPTANOATE, MAGNESIUM ALUMINUM
SILICATE, GLYCERYL STEARATE, PEG-100
STEARATE, CAPRYLYL GLYCOL, ARACHIDYL
ALCOHOL, POLYHYDROXYSTEARIC ACID,
ARACHIDYL GLUCOSIDE,
TRIETHOXYCAPRYLYLSILANE,
BEHENYL ALCOHOL, XANTHAN
GUM, BHT, DISODIUM EDTA,
PARFUM/FRAGRANCE, CITRAL,
CITRONELLOL, GERANIOL,
LIMONENE, LINALOOL,
METHYLPARABEN,
PHENOXYETHANOL,
SORBIC ACID.



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**Eight Hour
Cream**
Sun Defense for Face
SPF 50 Sunscreen PA+++
NET WT. 1.7 OZ. 53 g

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No. EIGN00018

Eight Hour Cream
Sun Defense for Face
SPF 50 Sunscreen PA+++

EIGHT HOUR CREAM SUN DEFENSE FOR FACE SPF 50 SUNSCREEN

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1094
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	6.159 g in 53 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.922 g in 53 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.65 g in 53 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
NEOPENTYL GLYCOL DIHEPTANOATE (UNII: 5LKW3C543X)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DOCOSANOL (UNII: 9G1OE216XY)	

TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL PARABEN (UNII: A2I8C7H9T)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
SORBIC ACID (UNII: X045WJ989B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1094-1	1 in 1 BOX		
1	NDC:67938-1094-2	53 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/14/2010	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 1/2011

Elizabeth Arden, Inc