

PURE FINISH MINERAL TINTED MOISTURIZER SPF 15- octinoxate 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.

BB0906

DESCRIPTION

For all skin types. Sheer, natural coverage. Pure, radiant finish. Pure minerals. Pure comfort. Pure perfection. This microlight mineral tinted moisturizer, infused with minerals, vitamins, and antioxidants brightens and evens out skintone with a hint of sheer, natural color. Instantly transforms skin's appearance with a fresh, luminous glow. SPF 15 sun protection. Oil free. Talc free. Fragrance free.

INDICATIONS AND USAGE

To Use: Smooth on to face before sun exposure.

WARNINGS

WARNING: For external use only. Avoid contact with eyes. Discontinue use if irritation or rash appear. If irritation persists, consult a doctor. Keep out of reach of children. Clinically, dermatologist, and allergy tested.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 6.0%, Titanium Dioxide 4.3%, Octisalate 4.0%.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Dimethicone, Mica, Cetearyl Alcohol, Polyglyceryl-4 Isostearate, Cetyl Dimethicon, Hexyl Laurate, Cetyl PEG/PPG-10/1 Dimethicon, Sodium Stearoyl Lactylate, Squalane, Hydrogenated Polyisobutene, Silene Uniflora Extract, Sodium Hyaluronate, Retinyl Palmitate, Tetrahexyldecyl Ascrobate, Tocopherol, Tocopheryl Acetate, Jojoba Esters, Glycerin, Triethoxycaprylylsilane, Carbomer, Magnesium Aluminum Silicate, Triethanolamine, Trisodium EDTA, Methyparaben, Phenoxyethanol, Propylparaben, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI77891).

DOSAGE & ADMINISTRATION

Smooth on to face.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

Provides SPF 15 sun protection.

OTC - WHEN USING

Avoid contact with eyes.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

For all skin types.
Sheer, natural coverage.
Pure, radiant finish.
Pure minerals. Pure comfort.
Pure perfection.

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ACTIVE INGREDIENTS:
OCTINOXATE 6.0%
TITANIUM DIOXIDE 4.3%
OCTISALATE 4.0%

OTHER INGREDIENTS:
WATER/AQUA/EAU, DIMETHICONE, CETEARYL ALCOHOL, POLYGLYCERYL-4 ISOSTEARATE, CETYL DIMETHICONE, HEXYL LAURATE, CETYL PEG/PPG-10/1 DIMETHICONE, SODIUM STEAROYL LACTYLATE, SQUALANE, HYDROGENATED POLYISOBUTENE, SILENE UNIFLORA EXTRACT, SODIUM HYALURONATE, RETINYL PALMITATE, TETRAHEXYLDECYL ASCORBATE, TOCOPHEROL, TOCOPHERYL ACETATE, JOJOBA ESTERS, GLYCERIN, TRIETHOXYCAPRYLYLSILANE, CARBOMER, MAGNESIUM ALUMINUM SILICATE, TRIETHANOLAMINE, TRISODIUM EDTA, MICA, METHYLPARABEN, PHENOXYETHANOL, PROPYPARABEN, IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

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Made in U.S.A.
ElizabethArden.com

Elizabeth Arden



**Pure Finish
Mineral
Tinted Moisturizer
SPF 15**

1.7 FL. OZ. 50 ml

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Mineral
Tinted Moisturizer
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No. TMPC00X

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octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-110
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3 mL in 50 mL

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.15 mL in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 mL in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
SQUALANE (UNII: GW89575KF9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-110-01	1 in 1 BOX		
1	NDC:67938-110-02	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/26/2010	

Labeler - Elizabeth Arden, Inc (849222187)