

FLAWLESS FINISH PERFECTLY SATINB 24HR MAKEUP SHADE- octinoxate, titanium dioxide cream

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.

Drug Facts

Active Ingredients

OCTINOXATE 5.00%

TITANIUM DIOXIDE 3.90%

Purpose

Sunscreen

Sunscreen

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

- **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:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - at least every 2 hours
 - use a water resistant sunscreen if swimming or sweating
- **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.

Inactive Ingredients

WATER/AQUA/EAU, CYCLO- PENTASILOXANE, ETHYLHEXYL ISONONANOATE, POLYMETHYL- SILSESQUIOXANE, DIMETHICONE, BUTYLENE GLYCOL, GLYCERIN, NYLON-12, ISODODECANE, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, ALCOHOL DENAT., MICA, C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER, BORON NITRIDE, ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER, ALUMINUM DIMYRISTATE, BAMBUSA ARUNDINACEA STEM POWDER, CITRIC ACID, CYCLOHEXA- SILOXANE, DIMETHICONE/ PEG-10/15 CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIPROPYLENE GLYCOL DISODIUM EDTA, DISODIUM STEAROYL GLUTAMATE, HYDROXYETHYL- CELLULOSE, LAUROYL LYSINE, LECITHIN, MAGNESIUM SULFATE, PENTYLENE GLYCOL, POLYSORBATE 60, SACCHARIDE ISOMERATE, SILICA, SODIUM CITRATE, SORBITAN STEARATE, TOCOPHEROL, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYL- SILANE, ZINC GLYCYRRHETINATE, BHT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE [MAY CONTAIN/PEUT CONTENIR (+/-) IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

Other Information

- Protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free 1-800 326-7337

Principal Display Panel - Box Label

Elizabeth Arden
NEW YORK

Flawless Finish
Perfectly Satin
24HR

Makeup

Broad Spectrum

Sunscreen SPF 15

1 FL. OZ.

30 ml

GLUE AREA / NO INK OR COATING

- For normal to oily skin.
 - Medium to full coverage.
 - Soft matte finish.
- 24 hours of color-true makeup infused with climate resistant technology that lasts through heat, humidity and moisture. Shine control ingredients are time released to absorb oil throughout the day for a flawless look. Transfer proof. Oil free.
- To use: Smooth onto face.
- Clinically, dermatologist and allergy tested.

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NEW YORK

**Flawless Finish
 Perfectly Satin
 24HR
 Makeup
 Broad Spectrum
 Sunscreen SPF 15**

**1 FL. OZ.
 30 ml**

Drug Facts (continued)

POLYDIMETHYLSILOXYETHYL DIMETHICONE, ALCOHOL DENAT., MICA, C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER, BORON NITRIDE, ACRYLATES/C12-22 ALKYL METHACRYLATE COPOLYMER, ALUMINUM DIMYRISTATE, BAMBUSA ARUNDINACEA STEM POWDER, CITRIC ACID, CYCLOHEXASILOXANE, DIMETHICONE/PEG-10/15 CROSSPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, DIPROPYLENE GLYCOL, DISODIUM EDTA, DISODIUM STEAROYL GLUTAMATE, HYDROXYETHYL-CELLULOSE, LAUROYL LYSINE, LECITHIN, MAGNESIUM SULFATE, PENTYLENE GLYCOL, POLYSORBATE 60, SACCHARIDE ISOMERATE, SILICA, SODIUM CITRATE, SORBITAN STEARATE, TOCOPHEROL, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, ZINC GLYCYRRHETINATE, BHT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE (MAY CONTAIN/PEUT CONTENIR (+/-) IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

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 New York, NY 10003
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 No. FFLC0XX
 elizabetharden.com

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FLAWLESS FINISH PERFECTLY SATINB 24HR MAKEUP SHADE

octinoxate, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.725 g in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.346 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ETHYLHEXYL ISONONANOATE (UNII: I6KB4GE3K4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISODODECANE (UNII: A8289P68Y2)	
NYLON-12 (UNII: 446U8J075B)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
ALCOHOL (UNII: 3K9958V90M)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
LAUROYL LYSINE (UNII: 113171Q70B)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ALUMINUM DIMYRISTATE (UNII: J2KA067N9O)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
BAMBUSA BAMBOS STEM (UNII: NRA4497HC5)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2063-1	1 in 1 BOX		
1	NDC:67938-2063-2	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/05/2015	

Labeler - ELIZABETH ARDEN, INC (849222187)

Establishment

Name	Address	ID/FEI	Business Operations
KOLMAR		001535103	MANUFACTURE(67938-2063)

Revised: 1/2015

ELIZABETH ARDEN, INC