

FLAWLESS FINISH PERFECTLY NUDE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SHADE NATURAL- octinoxate and titanium dioxide 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.

250402

DESCRIPTION

Makeup that feels like your own skin, only better. Light, breathable formula smooths on seamlessly for a naturally luminous look that lasts all day. Minimizes the look of pores and imperfections immediately and over time with continued use. Hydro-pigment color technology, vitamins and antioxidants protect and perfect, so skin looks beautifully even-toned and flawless.

INDICATIONS & USAGE

smooth onto face.

WARNINGS

For external use only

OTC - ACTIVE INGREDIENT

OCTINOXATE 4.00%.....Sunscreen

TITANIUM DIOXIDE 1.26%....Sunscreen

INACTIVE INGREDIENT

WATER/AQUA/EAU, ISOHEXADECANE, HEXYL LAURATE, MICA, GLYCERIN, POLYGLYCERYL-4 ISOSTEARATE, POTASSIUM CETYL PHOSPHATE, CETEARYL ALCOHOL, ASCORBYL PALMITATE, BETAINE, CARBOMER, GLYCERYL STEARATE, HYDROLYZED VEGETABLE PROTEIN, LECITHIN, MAGNESIUM ALUMINUM SILICATE, PEG-100 STEARATE, POLYGLYCERYL-10 MYRISTATE, SODIUM HYDROXIDE, TOCOPHERYL ACETATE, TREMELLA FUCIFORMIS SPOROCARP EXTRACT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM DEHYDROACETATE [MAY CONTAIN/PEUT CONTENIR (+/-) IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

OTC - DO NOT USE

Do not

use on damaged or broken skin

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

Provides SPF 15 sun protection.

OTC - STOP USE

Stop use and ask a doctor if rash occurs

OTC - WHEN USING

keep out of eyes. Rinse with water to remove.

Drug Facts (continued)

- For all skin types.
- Light to medium coverage. Natural radiant finish.
- Makeup that feels like your own skin, only better. Light, breathable formula smooths on seamlessly for a naturally luminous look that lasts all day.
- Minimizes the look of pores and imperfections immediately and over time with continued use.
- Hydro-pigment color technology, vitamins and antioxidants protect and perfect, so skin looks beautifully even-toned and flawless.
- To use: smooth onto face.
- Clinically, dermatologist and allergy tested.

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 4.00%	Sunscreen
TITANIUM DIOXIDE 1.26%	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.

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.

Inactive Ingredients
 WATER/AQUA/EAU, ISOHEXADECANE, HEXYL LAURATE, MICA, GLYCERIN, POLYGLYCERYL-4

Drug Facts (continued)

ISOSTEARATE, POTASSIUM CETYL PHOSPHATE, CETEARYL ALCOHOL, ASCORBYL PALMITATE, BETAINE, CARBOMER, GLYCERYL STEARATE, HYDROLYZED VEGETABLE PROTEIN, LECITHIN, MAGNESIUM ALUMINIUM SILICATE, PEG-100 STEARATE, POLYGLYCERYL-10 MYRISTATE, SODIUM HYDROXIDE, TOCOPHERYL ACETATE, TREMELLA FUCIFORMIS SPOROCARP EXTRACT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM BENZOATE, SODIUM DEHYDROACETATE [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

Flawless Finish Perfectly Nude Makeup Broad Spectrum Sunscreen SPF 15

1 FL. OZ. 30 ml

FLAWLESS FINISH PERFECTLY NUDE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SHADE NATURAL

octinoxate and titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2009
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 1500 mg
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	18.9 mg in 1500 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X10UF1E)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
BETAINE (UNII: 3SCV180C9W)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	

Product Characteristics

Color	BROWN (LIGHT BEIGE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2009-1	1 in 1 BOX		
1	NDC:67938-2009-2	1500 mg in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/17/2013	

Labeler - Elizabeth Arden, Inc (849222187)

Establishment

Name	Address	ID/FEI	Business Operations
Intercos		883457061	manufacture(67938-2009)

