

**FLAWLESS FINISH PERFECTLY NUDE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SHADE WARM SUNBEIGE- 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.*

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**250403**

**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

**Elizabeth Arden**  
NEW YORK

**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 WARM SUNBEIGE**

octinoxate and titanium dioxide lotion

| Product Information             |                   |                    |                |
|---------------------------------|-------------------|--------------------|----------------|
| Product Type                    | HUMAN OTC DRUG    | Item Code (Source) | NDC:67938-2010 |
| Route of Administration         | TOPICAL           |                    |                |
| Active Ingredient/Active Moiety |                   |                    |                |
| Ingredient Name                 | Basis of Strength | Strength           |                |

|   |                  |                    |
|---|------------------|--------------------|
| <b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)             | OCTINOXATE       | 60 mg in 1500 mg   |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 18.9 mg in 1500 mg |

### Inactive Ingredients

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

### Product Characteristics

|                 |                     |                     |  |
|-----------------|---------------------|---------------------|--|
| <b>Color</b>    | BROWN (LIGHT BEIGE) | <b>Score</b>        |  |
| <b>Shape</b>    |                     | <b>Size</b>         |  |
| <b>Flavor</b>   |                     | <b>Imprint Code</b> |  |
| <b>Contains</b> |                     |                     |  |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:67938-2010-1 | 1 in 1 BOX          |                      |                    |
| 1 | NDC:67938-2010-2 | 1500 mg in 1 BOTTLE |                      |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part352                                  | 07/17/2013           |                    |

**Labeler** - Elizabeth Arden, Inc (849222187)

### Establishment

| Name     | Address | ID/FEI    | Business Operations     |
|----------|---------|-----------|-------------------------|
| Intercos |         | 883457061 | manufacture(67938-2010) |

