

CERAMIDE LIFT AND FIRM MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 WARM HONEY- 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 4.0%

TITANIUM DIOXIDE 3.0%

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, CYCLOPENTASILOXANE, DIMETHICONE, ISOHEXADECANE, MICA, GLYCERIN, SORBITAN ISOSTEARATE, DIMETHICONE CROSSPOLYMER, ALUMINA, CAPRYLYL DIMETHICONE ETHOXY GLUCOSIDE, ALUMINUM/MAGNESIUM HYDROXIDE STEARATE, ACETYL OCTAPEPTIDE-3, ALANINE, ALPINIA SPECIOSA LEAF EXTRACT, ASCORBYL PALMITATE, ASPARTIC ACID, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, CARBOMER, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, CHOLESTEROL DEXTRIN, DISODIUM EDTA, FRUCTOSE, GLUCOSE, HEXYLENE GLYCOL, HIBISCUS ABELMOSCHUS SEED EXTRACT, LECITHIN, MANNITOL, PCA DIMETHICONE PHYTOSPHINGOSINE, POLYPERFLUOROETHOXYMET HOXY DIFLUOROETHYL PEG PHOSPHATE, POLYQUATERNIUM-51, RETINYL PALMITATE, SILICA Silylate, SODIUM CHLORIDE, SODIUM HYALURONATE, SODIUM LAUROYL LACTYLATE, SODIUM PCA, SORBITOL, SUCROSE, TOCOPHEROL, TREHALOSE, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT UREA, XANTHAN GUM, ZINC STEARATE, BHT, BENZOIC ACID CHLORPHENESIN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, 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 - Carton Label

Elizabeth Arden

NEW YORK

Ceramide

Lift and Firm Makeup

Broad Spectrum Sunscreen SPF 15

NET WT. 1 OZ. 32 g



Elizabeth Arden
NEW YORK

Ceramide
Lift and Firm Makeup
Broad Spectrum Sunscreen SPF 15

NET WT. 1 OZ. 32 g

- For normal to dry skin.
 - Medium to full coverage. Luminous finish.
 - Makeup goes ultra to smooth, lift and firm the look of skin. This moisturizing cream foundation with CPT technology, Ceramides and Advanced Moisture Complex diminishes the appearance of fine lines, perfects skin tone and creates a luminous finish that lasts all day. Provides Broad Spectrum Sunscreen SPF 15 protection.
- Clinically, dermatologist and allergy tested.

To use: Smooth onto face.

Distributed in U.S.A. by
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New York, NY 10003

Made in Italy
elizabetharden.com

Drug Facts (continued)

POLYQUATERNIUM-51, RETINYL PALMITATE, SILICA Silylate, SODIUM CHLORIDE, SODIUM HYALURONATE, SODIUM LAUROYL LACTYLATE, SODIUM PCA, SORBITOL, SUCROSE, TOCOPHEROL, TREHALOSE, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, UREA, XANTHAN GUM, ZINC STEARATE, BHT, BENZOIC ACID CHLORPHENESIN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE,

Drug Facts (continued)

PROPYLPARABEN, IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

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Drug Facts (continued)

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Drug Facts (continued)

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Drug Facts (continued)

PALMITATE, ASPARTIC ACID, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, CARBOMER, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, CHOLESTEROL DEXTRIN, DISODIUM EDTA, FRUCTOSE, GLUCOSE, HEXYLENE GLYCOL, HIBISCUS ABELMOSCHUS SEED EXTRACT, LECITHIN, MANNITOL, PCA DIMETHICONE PHYTOSPHINGOSINE, POLYPERFLUOROETHOXYMETHOXY DIFLUOROETHYL PEG PHOSPHATE,

CERAMIDE LIFT AND FIRM MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 WARM HONEY

octinoxate, titanium dioxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67938-0944 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 1.28 g in 32 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | .96 g in 32 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| ACETYL OCTAPEPTIDE-3 (UNII: 8K14HJF88S) | |
| ALANINE (UNII: OF5P57N2ZX) | |
| ALPINIA ZERUMBET LEAF (UNII: MS8P33AMKX) | |
| ALUMINUM OXIDE (UNII: LM26O6933) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| ASPARTIC ACID (UNII: 30KYC7MIAI) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| CERAMIDE 1 (UNII: 5THT33P7X7) | |
| CERAMIDE 3 (UNII: 4370DF050B) | |
| CERAMIDE 6 II (UNII: F1X8L2B00J) | |
| CHLORPHENESIN (UNII: I670DAL4SZ) | |
| CHOLESTEROL (UNII: 97C5T2UQ7J) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PC10R) | |
| ICODEXTRIN (UNII: 2NX48Z0A9G) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FRUCTOSE (UNII: 6YSS42VSEV) | |
| DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| ABELMOSCHUS MOSCHATUS SEED (UNII: UN2QZ55I88) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| ISOHEXADECANE (UNII: 918X10UF1E) | |
| MANNITOL (UNII: 3OWL53L36A) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| MICA (UNII: V8A1AW0880) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| PROPYL PARABEN (UNII: Z8IX2SC10H) | |

| | |
|---|--|
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO) | |
| SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| SORBITOL (UNII: 506T60A25R) | |
| SUCROSE (UNII: C151H8M554) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| TREHALOSE (UNII: B8WCK70T7I) | |
| TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828) | |
| UREA (UNII: 8W8T17847W) | |
| WATER (UNII: 059QF0K00R) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ZINC STEARATE (UNII: H92E6QA4FV) | |

| Packaging | | | | |
|-----------|------------------|--|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:67938-0944-1 | 1 in 1 BOX | | |
| 1 | NDC:67938-0944-2 | 32 g in 1 JAR; Type 0: Not a Combination Product | | |
| 2 | NDC:67938-0944-3 | 25000 g in 1 PAIL; 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 | 06/24/2015 | |

Labeler - ELIZABETH ARDEN, INC (849222187)

| Establishment | | | |
|---------------|---------|-----------|-------------------------|
| Name | Address | ID/FEI | Business Operations |
| KOLMAR | | 001535103 | MANUFACTURE(67938-0944) |