

CERAMIDE LIFT AND FIRM MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15

SANDSTONE- octinoxate and 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.

BB0939

DESCRIPTION

- 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 diminished the appearance of fine lines, perfects skin tone, and creates a luminous finish that lasts all day. Provides Broad Spectrum Sunscreen SPF 15 protection.

INDICATIONS AND USAGE

To Use: Smooth onto face.

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.

WARNINGS

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.

OTC - ACTIVE INGREDIENT

Active Ingredients: Octinoxate 4.0%, Titanium Dioxide 3.0%.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Cyclopentasiloxane, Dimethicone, Isohexadecane, Mica, Glycerin, Sorbitan, Isostearate, Dimethicone Crosspolymer, Alumina, Caprylyl Dimethicone Ethoxy Glucoside, Aluminum/Magnesium Hydroxide Stearate, Ceramide 1, Ceramide 3, Ceramide 6 II, Alpinia Speciosa Leaf Extract, Hibiscus Abelmoschus Seed Extract, Trifolium Pratense (Clover) Flower Extract, Sodium Hyaluronate, Ascorbyl Palmitate, Retinyl palmitate, Tocopherol, Alanine, Aspartic Acid, Glumatic Acid, Silica Silyate, Acetyl Octapeptide-3, Mannitol, Sodium PCA, Sorbitol, Trehalose, Urea, Lecithin, PCA Dimethicone, Phytosphingosine, Polyperfluoroethoxymethoxy Difluoroethyl PEG

Phosphate, Fructose, Glucose, Sucrose, Cholesterol, Sodium Lauroyl Lactylate, Polyquaternium-51, Dextrin, Butylene Glycol, Hexylene Glycol, Carbomer, Xanthan Gum, BHT, Sodium Chloride, Zinc Stearate, Benzoic Acid, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Chlorphenesin, Iron Oxides (CI 77481, CI 77482), Titanium Dioxide (CI 77891).

DOSAGE & ADMINISTRATION

Smooth on to face.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.


OTC - PURPOSE

Provides SPF 15 sun protection.

OTC - WHEN USING

Keep out of eyes.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



Elizabeth Arden
NEW YORK

Ceramide
Lift and Firm Makeup
Broad Spectrum Sunscreen SPF 15

- For normal to dry skin
- Medium to full coverage. Luminous finish.
- Makeup goes ultra 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.

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Made in Italy

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Drug Facts (continued)

POLYPERFLUOROETHOXYMETHOXY
 DIFLUOROETHYL PEG
 PHOSPHATE, FRUCTOSE,
 GLUCOSE, SUCROSE,
 CHOLESTEROL, SODIUM
 LAUROYL LACTYLATE,
 POLYQUATERNIUM-51,
 DEXTRIN, BUTYLENE GLYCOL,
 HEXYLENE GLYCOL, CARBOMER,
 XANTHAN GUM, BHT, SODIUM
 CHLORIDE, ZINC STEARATE,
 BENZOIC ACID, BUTYLPARABEN,
 ETHYLPARABEN,
 ISOBUTYLPARABEN,
 METHYLPARABEN.

Drug Facts (continued)

PHENOXYETHANOL,
 POTASSIUM SORBATE,
 PROPYLPARABEN,
 CHLORPHENESIN, 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

Drug Facts**Active Ingredients Purpose**

OCTINOXATE 4.0%..... Sunscreen
 TITANIUM DIOXIDE 3.0%.... 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

Drug Facts (continued)**■ 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

Drug Facts (continued)**■ 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.

Drug Facts (continued)**Inactive Ingredients**

WATER/AQUA/EAU,
 CYCLOPENTASILOXANE,
 DIMETHICONE,
 ISOHEXADECANE, MICA,
 GLYCERIN, SORBITAN
 ISOSTEARATE, DIMETHICONE
 CROSSPOLYMER, ALUMINA,
 CAPRYLYL DIMETHICONE
 ETHOXY GLUCOSIDE,
 ALUMINUMMAGNESIUM
 HYDROXIDE STEARATE,
 CERAMIDE 1, CERAMIDE 3,
 CERAMIDE 6 II, ALPINIA
 SPECIOSA LEAF EXTRACT.

Drug Facts (continued)

HIBISCUS ABELMOSCHUS SEED
 EXTRACT, TRIFOLIUM
 PRATENSE (CLOVER) FLOWER
 EXTRACT, SODIUM
 HYALURONATE, ASCORBYL
 PALMITATE, RETINYL
 PALMITATE, TOCOPHEROL,
 ALANINE, ASPARTIC ACID,
 GLUTAMIC ACID, SILICA
 Silylate, ACETYL
 OCTAPEPTIDE-3, MANNITOL,
 SODIUM PCA, SORBITOL,
 TREHALOSE, UREA, LECITHIN,
 PCA DIMETHICONE,
 PHYTOSPHINGOSINE.

Elizabeth Arden

Ceramide

Lift and Firm Makeup

Broad Spectrum

Sunscreen SPF 15



To use: Smooth onto face.

ACTIVE INGREDIENTS: OCTINOXATE 4.0 % W/W
TITANIUM DIOXIDE 3.0 % W/W

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. **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.

Other information: protect this product from excessive heat and direct sun. **Questions or comments?** Call toll free 1-800-326-7337.

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CERAMIDE LIFT AND FIRM MAKEUP BROAD SPRECTRUM SUNSCREEN SPF 15 SANDSTONE

octinoxate and titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67938-0939

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	0.96 g in 32 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
CERAMIDE 3 (UNII: 4370DF050B)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
ALANINE (UNII: OF5P57N2ZX)	
ASPARTIC ACID (UNII: 30KYC7MIAI)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
MANNITOL (UNII: 3OWL53L36A)	
SORBITOL (UNII: 506T60A25R)	
TREHALOSE (UNII: B8WCK70T7I)	
UREA (UNII: 8W8T17847W)	
FRUCTOSE (UNII: 6YSS42VSEV)	
SUCROSE (UNII: C151H8M554)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ZINC STEARATE (UNII: H92E6QA4FV)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLPARABEN (UNII: 3QPII03FV8)	
ETHYLPARABEN (UNII: 14255EXE39)	
ISOBUTYLPARABEN (UNII: 0QQJ25X58G)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CHLORPHENESIN (UNII: I670DAL4SZ)	

Product Characteristics

Color	BROWN (Sandstone)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0939-1	1 in 1 BOX		
1	NDC:67938-0939-2	32 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/05/2010	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 5/2013

Elizabeth Arden, Inc