

CERAMIDE LIFT AND FIRM DAY BROAD SPECTRUM SUNSCREEN SPF 30- octinoxate, oxybenzone, octisalate, octocrylene, and avobenzone 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.

BC0964

DESCRIPTION

A moisture treatment for face, neck, and décolletage to quickly infuse skin with ceramides for a youth-restoring boost. Hydrates intensely throughout the day, leaving skin feeling softer and firmer. Diminishes the appearance of surface lines and targets deeper wrinkles. Helps restore radiance for a more youthful looking complexion.

INDICATIONS AND USAGE

To Use: Apply to cleansed skin after Ceramide Capsules in the morning.

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.

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 7.5 %, Oxybenzone 5.0%, Octisalate 5.0%, Octocrylene 2.2%, Avobenzone 2.0%.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Dimethicone, C12-15 Alkyl Benzoate, Butylene Glycol, Cyclopentasiloxane, Isostearyl Neopentanoate, Theobroma Cacao (Cocoa) Seed Butter, Dimethicone/Vinyl Dimethicon Crosspolymer, Butyrospermum Parkii (Shea Butter) Extract, PPG-2 Isoceteth-20 Acetate, Glycerin Caprylic/Capric Triglyceride, Ceramide 1, Ceramide 3, Ceramide 6 II, Apinia Speciosa Leaf Extract, Hibiscus Abelmoschus Seed Extract, Trifolium Pratense (Clover) Flower Extract, Sodium Hyaluronate, Ascorbyl Palmitate, Retinyl Linoleate Retinyl Palmitate, Tocopherol, Tocopheryl Acetate, Cetearyl Dimethicon Crosspolymer, Isohexadecane, Acetyloctapeptide-3, Propylene Glycol, Sodium PCA, Trehalose Urea, Hydrogenated Lecithin, Lecithin

Phospholipids, Phytosphingosin, Polyphosphorylcholine Glycol Acrylate, Sucrose, Cetearyl Alcohol, Cholesterol, Sodium lauroyl Lactylate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polysorbate 80, Trideceth-6, Acrylamide/Sodium Acrylate Copolymer, Polyquaternium-51, PEG-8, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Xanthan Gum, Sodium Hydroxide, BHT, Mineral Oil/Paraffinum Liquidum/Huile Minerale, Dimethiconol, Phenyl Trimethicone, Parfum/Fragrance, Alpha-Isomethyl Ionone, Benzyl Benzoate, Butylphenyl Methylpropional, Citral, Citronellol, Eugenol, Geraniol, Hexyl Cinnamal Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Limonene, Linalool, Benzoic Acid, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Chlorphenesin, Red 4 (CI 14700), Yellow 6 (CI15985).

DOSAGE & ADMINISTRATION

Apply to skin.

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 immediately.

OTC - PURPOSE

Provides SPF 30 sun protection.

OTC - WHEN USING

Keep out of eyes.

<p>A moisture treatment for face, neck and décolletage to quickly infuse skin with ceramides for a youth-restoring boost. Hydrates intensely throughout the day, leaving skin feeling softer and smoother. Diminishes the appearance of surface lines and targets deeper wrinkles. Helps restore radiance for a more youthful looking complexion.</p> <p>To use: Apply to cleansed skin after Ceramide Capsules in the morning. Clinically, dermatologist and allergy tested.</p> <p>Drug Facts (continued)</p> <p>Other information</p> <ul style="list-style-type: none"> Protect this product from excessive heat and direct sun. <p>Questions or comments?</p> <ul style="list-style-type: none"> Call toll free 1-800-328-7337 	<p style="text-align: center;">Elizabeth Arden NEW YORK</p> <p style="text-align: center;">Ceramide Lift and Firm Day Cream Broad Spectrum Sunscreen SPF 30</p>	<p>Drug Facts</p> <p>Active Ingredients</p> <table border="0"> <tr> <td>OCTINOATE 7.5%</td> <td>Sunscreen</td> </tr> <tr> <td>OXYBENZONE 5.0%</td> <td>Sunscreen</td> </tr> <tr> <td>OCTOXYLATE 5.0%</td> <td>Sunscreen</td> </tr> <tr> <td>OCTOXYLENE 2.2%</td> <td>Sunscreen</td> </tr> <tr> <td>AZOBIZONE 2.0%</td> <td>Sunscreen</td> </tr> </table> <p>Uses</p> <ul style="list-style-type: none"> 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. <p>Warnings</p> <ul style="list-style-type: none"> For external use only Do not use on children or children ages When using this product, keep out of eyes. Rinse with water to remove. 	OCTINOATE 7.5%	Sunscreen	OXYBENZONE 5.0%	Sunscreen	OCTOXYLATE 5.0%	Sunscreen	OCTOXYLENE 2.2%	Sunscreen	AZOBIZONE 2.0%	Sunscreen	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> 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. <p>Directions For Sunscreen Use:</p> <ul style="list-style-type: none"> Apply liberally 15 minutes before sun exposure Reapply <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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. <p>Inactive Ingredients</p> <p>WATER/AQUAEAL, DIMETHICONE, C10-15 ALKYL BENZOATE, BUTYLENE GLYCOL, CYCLOPENTASILOXANE, ISOSTEARYL NEOPENTANOATE, THEOPHROMA CACAO (COCOA) SEED BUTTER, DIMETHICONE/ETHYL DIMETHICONE COPOLYMER, BUTYROPERM FANU (SHEA BUTTER) EXTRACT, PPG-2, SODIUM DIOCTATE, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, CERAMIDE 1.</p>	<p>Drug Facts (continued)</p> <p>CERAMIDE 1, CERAMIDE 6 II, ALPHA BIPICCOLA LEAF EXTRACT, HIBISCUS ABELMOSCHUS SEED EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, SODIUM HYALURONATE, ASCORBIC PALMITATE, RETINYL LINOLEATE, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, CETEARYL DIMETHICONE COPOLYMER, ISOEUCADIC ACETYL OCTAPENYD-3-PROPYLENE GLYCOL, SODIUM PCA, TRISALIC ACID, HYDROGENATED LECITHIN, LECITHIN, PHOSPHOLIPID, PHYTOSPHINGOSINE, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, SUCROSE, CETEARYL ALCOHOL, CHOLESTEROL, SODIUM LAUROYL LACTYLATE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POLYSORBATE 80, TRIDECETHYL ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER, POLYQUATERNIUM-51, PEG-8, ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER, CARBOMER, XANTHAN GUM, SODIUM HYDROXIDE, BHT, MINERAL OIL/PARAFFINUM LIQUIDUM/HUILE MINERALE, DIMETHICONOL, PHENYL TRIMETHICONE, PARFUM/FRAGRANCE, ALPHA-ISOMETHYL IONONE, BENZYL BENZOATE, BUTYLPHENYL METHYLPROPIONAL, CITRAL, CITRONELLOL, EUGENOL, GERANIOL, HEXYL CINNAMAL HYDROXYISOHXYL 3-CYCLOHEXENE CARBOXYALDEHYDE, LIMONENE, LINALOOL, BENZOIC ACID, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, CHLORPHENESIN, RED 4 (CI 14700), YELLOW 6 (CI 15985).</p>
OCTINOATE 7.5%	Sunscreen													
OXYBENZONE 5.0%	Sunscreen													
OCTOXYLATE 5.0%	Sunscreen													
OCTOXYLENE 2.2%	Sunscreen													
AZOBIZONE 2.0%	Sunscreen													
<p>0 12545 67891 2</p> <p>16878912</p> <p>MADE IN U.S.A.</p> <p>Elizabeth Arden Inc. 270 Madison Ave. New York, NY 10017 • ElizabethArden.com</p>														

Drug Facts (continued)

OCTAPEPTIDE-3, PROPYLENE GLYCOL, SODIUM PCA, TREHALOSE, UREA, HYDROGENATED LECITHIN, LECITHIN, PHOSPHOLIPIDS, PHYTOSPHINGOSINE, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, SUCROSE, CETEARYL ALCOHOL, CHOLESTEROL, SODIUM LAUROYL LACTYLATE, HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, POLYSORBATE 80, TRIDECETH-8, ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER, POLYQUATERNIUM-51, PEG-8, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, CARBOMER, XANTHAN GUM, SODIUM HYDROXIDE, BHT, MINERAL OIL/ PARAFFINUM LIQUIDUM/HUILE MINÉRALE, DIMETHICONOL, PHENYL TRIMETHICONE, PARFUM/FRAGRANCE, ALPHA-ISOMETHYL IONONE, BENZYL BENZOATE, BUTYLPHENYL METHYLPROPIONAL, CITRAL, CITRONELLOL, EUGENOL, GERANIOL, HEXYL CINNAMAL, HYDROXYISOHXYL 3-CYCLOHEXENE CARBOXALDEHYDE, LIMONENE, LINALOOL, BENZOIC ACID, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, CHLORPHENESIN, RED 4 (CI 14700), YELLOW 8 (CI 15985).

Other Information

- Protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free 1-800-326-7337

195553

Drug Facts

Active Ingredients	Purpose
OCTINOXATE 7.50%	Sunscreen
OXYBENZONE 5.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 2.2%	Sunscreen
AVOBENZONE 2.0%	Sunscreen

Uses

- Helps prevent sunburn

Drug Facts (continued)

- 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.

Inactive Ingredients

WATER/AQUA/EAU, DIMETHICONE, C12-15 ALKYL BENZOATE, BUTYLENE GLYCOL, CYCLOPENTASILOXANE, ISOSTEARYL NEOPENTANOATE, THEOBROMA CACAO (COCOA) SEED BUTTER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, BUTYROSPERMUM PARKII (SHEA BUTTER) EXTRACT, PPG-2 ISOCETETH-20 ACETATE, GLYCERIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, ALPINIA SPECIOSA LEAF EXTRACT, HIBISCUS ABELMOSCHUSS SEED EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, SODIUM HYALURONATE, ASCORBYL PALMITATE, RETINYL LINOLEATE, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, CETEARYL DIMETHICONE CROSSPOLYMER, ISOHEXADECANE, ACETYL

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. **Questions or comments?** Call toll free 1-800-326-7337

© Elizabeth Arden, Inc., Dist., N.Y., NY 10003 • elizabetharden.com Made in U.S.A. NO. 7890MP2200

Ceramide
Lift and Firm Day Cream
Broad Spectrum Sunscreen
SPF 30

To use: Pat gently around the eye area.

ACTIVE INGREDIENTS:
OCTINOXATE 7.5 % W/W
OXYBENZONE 5.0 % W/W
OCTISALATE 5.0 % W/W
OCTOCRYLENE 2.2 % W/W
AVOBENZONE 2.0 % 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.

WARNING: FOR EXTERNAL USE ONLY DO NOT USE ON DAMAGED OR BROKEN SKIN. WHEN USING THIS PRODUCT

CERAMIDE LIFT AND FIRM DAY BROAD SPECTRUM SUNSCREEN SPF 30

octinoxate, oxybenzone, octisalate, octocrylene, and avobenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0964
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.675 g in 49 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	2.45 g in 49 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.45 g in 49 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.078 g in 49 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.98 g in 49 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEANUT OIL (UNII: O88E196QRF)	
PPG-2 ISOCETETH-20 ACETATE (UNII: B16C7YO419)	
GLYCERIN (UNII: PDC6A3C0OX)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CERAMIDE 1 (UNII: 5THT33P7X7)	
CERAMIDE 3 (UNII: 4370DF050B)	
CERAMIDE 6 II (UNII: F1X8L2B00J)	
ALPINIA ZERUMBET LEAF (UNII: MS8P33AMKX)	
ABELMOSCHUS MOSCHATUS SEED (UNII: UN2QZ55I88)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
RETINYL LINOLEATE (UNII: 61911N8D6W)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOHEXADECANE (UNII: 918X10UF1E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
TREHALOSE (UNII: B8WCK70T7I)	
UREA (UNII: 8W8T17847W)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
SUCROSE (UNII: C151H8M554)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPa.S AT 1%) (UNII: 86FQE96TZ4)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
BENZYL BENZOATE (UNII: N863NB338G)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
CITRAL (UNII: T7EU0O9VPP)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
EUGENOL (UNII: 3T8H1794QW)	
GERANIOL (UNII: L837108USY)	

.ALPHA.-HEXYL CINNAMALDEHYDE (UNII: 7X6O37OK2I)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
BENZOIC ACID (UNII: 8SKN0B0MM)
BUTYL PARABEN (UNII: 3QP1U3FV8)
ETHYL PARABEN (UNII: 14255EXE39)
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)
METHYL PARABEN (UNII: A2I8C7HI9T)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
CHLORPHENESIN (UNII: I670DAL4SZ)
FD&C RED NO. 4 (UNII: X3W0AM1JLX)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0964-1	1 in 1 BOX		
1	NDC:67938-0964-2	49 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/27/2009	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 4/2013

Elizabeth Arden, Inc