

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

BB0802

DESCRIPTION

A lightweight, oil-free lotion for face, neck, and decolletage to quickly infuse skin with ceramides for a youth-restoring boost. Absorbs quickly to provide intense hydration throughout the day, leaving skin feeling soft and firm. Diminished the appearance of surface lines and 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%, Avobenzone 2.0%.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Butylene Glycol, C12-15 Alkyl Benzoate, Cyclopentasiloxane, Cetearyl Alcohol, Dimethicone, Styrene/Acrylates Copolymer, Glycerin, Dimethicone/Vinyl Dimethicone Crosspolymer, PPG-2 Isoceteth-20 Acetate, Theobroma Cacao (Cocoa) Seed Butter, Butyrospermum Parkii (Shea Butter) Extract, Caprylyl Methicone, Ceramide 1, Ceramide 3, Ceramide 6 II, Alpinia Speciosa Leaf Extract, Hibiscus Abeloschuss Seed Extract, Trifolium Pratense (Clover) Flower Extract, Sodium Hyaluronate, Ascorbyl Palmitate, Retinyl Linoleate, Retinyl Palmitate, Tocopherol, Tocopheryl Acetate, Hydrogenated Lecithin, Lecithin, Phospholipids, Phytosphingosine, Polyphosphorylcholine Glycol Acrylate, Sucrose, Cholesterol, Sodium Lauroyl Lactylate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG-8 Laurate, Polysorbate 80,

Potassium Cetyl Phosphate, Sodium Dodecylbenzenesulfonate, Polyquaternium-51, PEG-8, Carbomer, Xanthan Gum, Sodium Hydroxide, BHT, Disodium EDTA, Dimethiconol, Phenyl Trimethicone, Parfum/Fragrance, Alpha-Isomethyl Ionone, Benzyl Benzoate, Butylphenyl Methylpropional Citral, Citronellol, Eugenol, Geraniol, Hexyl Cinnamyl, Hydroxyisohexyl 3-Cyclohexene, Carboxaldehyde Limonene, Linalool, Benzoic Acid, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sorbic Acid, Chlorphenesin, Red 4 (CI 14700), Yellow 6 (CI 15985).

DOSAGE & ADMINISTRATION

Apply to skin.

OTC - KEEP OUT OF REACH OF CHILDREN

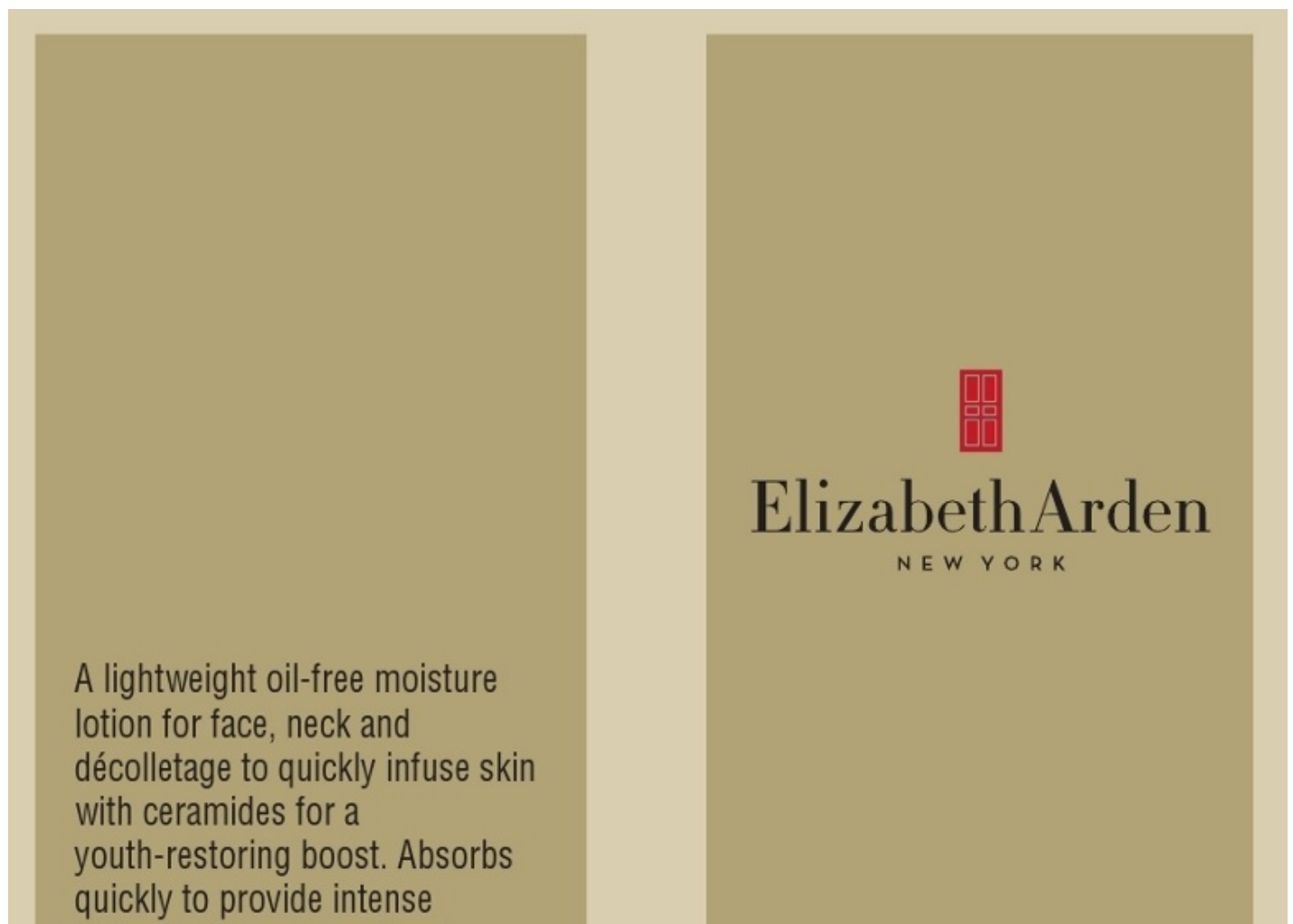
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control center immediately.

OTC - PURPOSE

Provides SPF 30 sun protection.

OTC - WHEN USING

Keep out of eyes.



hydration throughout the day,
leaving skin feeling soft and firm.
Diminishes the appearance of
surface lines and helps restore
radiance for a more youthful
looking complexion.

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

Clinically, dermatologist and
allergy tested.

Ceramide
Lift and Firm
Day Lotion
Broad Spectrum
Sunscreen SPF 30

Drug Facts (continued)

UREA, HYDROGENATED LECITHIN, LECITHIN, PHOSPHOLIPIDS, PHYTOSPHINGOSINE, POLYPHOSPHORYLCHOLINE GLYCOL ACRYLATE, SUCROSE, CHOLESTEROL, SODIUM LAUROYL LACTYLATE, HYDROXYETHYL ACRYLATE/ SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER, PEG-8 LAURATE, POLYSORBATE 80, ▶

Drug Facts (continued)

POTASSIUM CETYL PHOSPHATE, SODIUM DODECYLBENZENESULFONATE, POLYQUATERNIUM-51, PEG-8, CARBOMER, XANTHAN GUM, SODIUM HYDROXIDE, BHT, DISODIUM EDTA, DIMETHICONE, PHENYL TRIMETHICONE, PARFUM/ FRAGRANCE, ALPHA-ISOMETHYL IONONE, BENZYL BENZOATE, BUTYLPHENYL METHYLPROPIONAL, CITRAL, CITRONELLOL, EUGENOL, GERANIOL, HEXYL ▶

Drug Facts (continued)

CINNAMAL, HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXALDEHYDE, LIMONENE, LINALOOL, BENZOIC ACID, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, POTASSIUM SORBATE, PROPYLPARABEN, SORBIC ACID, CHLORPHENESIN, RED 4 (CI 14700), YELLOW 6 (CI 15985). ▶

Drug Facts (continued)**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 7.5% ... Sunscreen
 OXYBENZONE 5.0% ... Sunscreen
 OCTISALATE 5.0% ... Sunscreen
 AVOBENZONE 2.0% ... 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 ▶

Drug Facts (continued)**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. ▶

Drug Facts (continued)**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 ▶

Drug Facts (continued)

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, BUTYLENE GLYCOL, C12-15 ALKYL BENZOATE, CYCLOPENTASILOXANE. ▶

Drug Facts (continued)

CETEARYL ALCOHOL, DIMETHICONE, STYRENE/ACRYLATES COPOLYMER, GLYCERIN, DIMETHICONE/ VINYL DIMETHICONE CROSSPOLYMER, PPG-2 ISOCETETH-20 ACETATE, THEOBROMA CACAO (COCOA) SEED BUTTER, BUTYROSPERMUM PARKII (SHEA BUTTER) EXTRACT, CAPRYLYL METHICONE, CERAMIDE 1, CERAMIDE 3, CERAMIDE 6 II, ALPINA SPECIOSA LEAF EXTRACT. ▶

Drug Facts (continued)

HIBISCUS ABELMOSCHUS SEED EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, SODIUM HYALURONATE, ASCORBYL PALMITATE, RETINYL LINOLEATE, RETINYL PALMITATE, TOCOPHEROL, TOCOPHERYL ACETATE, HYDROGENATED PALM GLYCERIDES, ISOHEXADECANE, ACETYL OCTAPEPTIDE-3, PROPYLENE GLYCOL, SODIUM PCA, TREHALOSE. ▶



Elizabeth Arden
NEW YORK

Ceramide
Lift and Firm
Day Lotion
Broad Spectrum
Sunscreen SPF 30

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

ACTIVE INGREDIENTS: OCTINOXATE 7.5 % W/W,
OXYBENZONE 5.0 % W/W, OCTISALATE 5.0 % 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.

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 DAY BROAD SPECTRUM SUNSCREEN SPF 30

octinoxate, oxybenzone, octisalate, and avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0802
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	2.5 g in 50 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.5 g in 50 g

AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)

AVOBENZONE

1 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
COCOA BUTTER (UNII: 512OYT1CRR)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
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)	
HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q)	
ISOHEXADECANE (UNII: 918X10UF1E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
TREHALOSE (UNII: B8WCK70T7I)	
UREA (UNII: 8W8T17847W)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)	
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S)	
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)	
SUCROSE (UNII: C151H8M554)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
SODIUM LAUROYL LACTYLATE (UNII: 7243K85WFO)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
BENZYL BENZOATE (UNII: N863NB338G)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
CITRAL (UNII: T7EU0O9VPP)
EUGENOL (UNII: 3T8H1794QW)
GERANIOL (UNII: L837108USY)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)
BENZOIC ACID (UNII: 8SKN0B0MIM)
BUTYLPARABEN (UNII: 3QPIU3FV8)
ETHYLPARABEN (UNII: 14255EXE39)
ISOBUTYLPARABEN (UNII: 0QJ25X58G)
METHYLPARABEN (UNII: A2I8C7HI9T)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
SORBIC ACID (UNII: X045WJ989B)
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:67938-0802-1	1 in 1 BOX		
1	NDC:67938-0802-2	50 g in 1 TUBE		

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)