

**VISIBLE DIFFERENCE GENTLE HYDRATING BROAD SPECTRUM SUNSCREEN SPF 15-  
octinoxate, avobenzone, and oxybenzone 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.*

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**BC1169**

**DESCRIPTION**

This multi-benefit moisturizer for dry skin provides intense hydration. Leaves skin feeling soft and smooth.

**INDICATIONS AND USAGE**

To Use: Smooth onto cleansed face and throat.

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 measures including: Limit time in the sun, especially from 10 a.m. – 2 p.m. Wear long-sleeve shirts, pants, decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection hats, and sunglasses.

Children under 6 months ask a doctor.

**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%, Avobenzone 3.0%, Oxybenzone 3.0%.

**INACTIVE INGREDIENT**

Inactive Ingredients: Water/Aqua/Eau, Butylene Glycol, Glycerin, Isononyl Isononanoate, Dimethicone, Cetearyl Glucoside, Pentylene Glycol, Butyl Stearate, Tridecyl Salicylate, Cetyl Ricinoleate, Cyclopentasiloxane, Narcissus Tazetta Bulb Extrat, Trifolium Pratense (Clover) Flower Extract, Sodium Hyaluronate, Tocopherol, Tocopheryl Acetate, Caprylyl Glycol, Cetearyl Dimethicone Crosspolymer, Ethylhexyl Palmitate, Glyceryl Stearate, Sodium PCA, Trehalose, Urea, Hyrdolyzed Soy Protein, Lecithin, Phospholipids, Polyphophorylcholine Glycol Acrylate, Ammonium Acryloyldimethylaurate/VP Copolymer, PEG-100 Stearate, PEG-8 Laurate, PEG-60 Hydrogenated Castor Oil, Sodium Dodecylbenzenesulfonate, Polyquaternium-51, Styrene/Acrylates Copolymer, Hexylene Glycol, Isododecane, PEG-8, Xanthan Gum, Nylon-12, BHT, Disodium EDTA, Mica, Tin Oxide, Silica Dimethyl Silylate, Parfum/Fragrance, Benzyl Salicylate, Butylphenyl Methylpropional, Citonellol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Limmene, Linalool, Benzoic Acid, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Potassium Sorbate, Propylparaben, Sorbic Acid, Chlorphenesin, Titanium Dioxide (CI 77891).

**DOSAGE AND ADMINISTRATION**

Smooth on to face and throat.

**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.

**WHEN USING**

Keep out of eyes.

Visible Difference  
Gentle Hydrating Cream  
Broad Spectrum  
Sunscreen SPF 15



**Elizabeth Arden**  
NEW YORK

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To use: Smooth onto cleansed face and throat.

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New York, NY 10003  
[elizabetharden.com](http://elizabetharden.com)

Made in U.S.A.  
No. 7375MP1200



Visible Difference

Gentle Hydrating Cream

Broad Spectrum

dry

Sunscreen SPF 15

**Elizabeth Arden**

ACTIVE INGREDIENTS: OCTINOXATE, 7.5% W/W,  
AVOBENZONE, 3.0% W/W, OXYBENZONE, 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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Sample. Not for sale.

Made in U.S.A.

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## VISIBLE DIFFERENCE GENTLE HYDRATING BROAD SPECTRUM SUNSCREEN SPF 15

octinoxate, avobenzone, and oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67938-1169
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.75 g in 50 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.5 g in 50 g
<b>OXYBENZONE</b> (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	1.5 g in 50 g

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>BUTYL STEARATE</b> (UNII: 6Y0AI5605C)	
<b>TRIDECYL SALICYLATE</b> (UNII: AZQ08K38Z1)	
<b>CETYL RICINOLEATE</b> (UNII: 1P677500YD)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>NARCISSUS TAZETTA BULB</b> (UNII: K17762966S)	
<b>TRIFOLIUM PRATENSE FLOWER</b> (UNII: 4JS0838828)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>TREHALOSE</b> (UNII: B8WCK70T7I)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER</b> (UNII: W59H9296ZG)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
<b>SODIUM DODECYLBENZENESULFONATE</b> (UNII: 554127163Y)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)	
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)	
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	
<b>HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE</b> (UNII: QUE43B9Z2Q)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>BUTYLPARABEN</b> (UNII: 3QPIIU3FV8)	
<b>ISOBUTYLPARABEN</b> (UNII: 0QQJ25X58G)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1169-1	1 in 1 CARTON		
1	NDC:67938-1169-2	50 g in 1 JAR		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/15/2011	

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

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Elizabeth Arden, Inc