

**PRO TRIPLE PROTECTION FACTOR FACE AND BODY BROAD SPECTRUM SPF 30
SUNSCREEN- octinoxate, oxybenzone, octisalate, octocrylene, 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.

Drug Facts

Active Ingredients

OCTINOXATE 7.5 % W/W

OXYBENZONE 5.0 % W/W

OCTISALATE 5.0 % W/W

OCTOCRYLENE 5.0 % W/W

AVOBENZONE 3.0 % W/W

Purpose

Sunscreen

Sunscreen

Sunscreen

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, NYLON-12, BUTYLENE GLYCOL, C12-15 ALKYL BENZOATE, DIMETHICONE, PENTYLENE GLYCOL, CETEARYL ALCOHOL, CAPRYLYL METHICONE, ACETYL FARNESYL CYSTEINE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, ARABIDOPSIS THALIANA EXTRACT, CAPRYLYL GLYCOL, CARNOSINE, CETETH-20 PHOSPHATE, CHONDRUS CRISPUS EXTRACT, COCO-GLUCOSIDE, DICETYL PHOSPHATE, DISODIUM EDTA, ERGOTHIONEINE, HYDROXYACETOPHENONE, LECITHIN, MICROCOCCUS LYSATE, PLANKTON EXTRACT, SODIUM HYALURONATE, SODIUM PCA, TOCOPHERYL ACETATE, BHT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM DEHYDROACETATE.

Other Information

- Protect this product from excessive heat and direct sun
- Store at room temperature

Questions or comments?

Call toll free 1-844-273-3679

Principal Display Panel - Bottle Label

Elizabeth Arden

PRO

TRIPLE
PROTECTION
FACTOR
FACE & BODY

Broad Spectrum
SPF 30 Sunscreen
Lotion

with DNA Enzyme Complex™
+ Antioxidants

4 FL. OZ. (120 ml)

Elizabeth Arden



PRO
TRIPLE
PROTECTION
FACTOR
FACE & BODY
Broad Spectrum
SPF 30 Sunscreen
Lotion
with DNA Enzyme Complex™
+ Antioxidants

4 FL. OZ. (120 ml)

Use Directions: Apply generously and evenly to face and body.

Active Ingredients: OCTINOXATE 7.5 % W/W, OXYBENZONE 5.0 % W/W, OCTISALATE 5.0 % W/W, OCTOCRYLENE 5.0 % W/W, AVOBENZONE, 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. Use a water resistant sunscreen if swimming or sweating. 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.

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7151-120-01 P10-15

Principal Display Panel - Carton Label

Elizabeth Arden

PRO

TRIPLE
PROTECTION
FACTOR
FACE & BODY

Broad Spectrum
SPF 30 Sunscreen
Lotion

with DNA Enzyme Complex™
+ Antioxidants

4 FL. OZ. (120 ml)

Triple Protection Factor Face & Body provides three non-negotiables for ultimate skin protection:

1. Sun Protection Factor (SPF) 30
2. Antioxidant protection against free radicals and environmental pollutants
3. Correction to the appearance of environmental skin damage

Helps protect skin from environmental exposure and signs of premature skin aging and designed to maintain radiant, glowing skin day after day with a non-tinted formulation.

This multi-functional product is an essential step in all skin health and beauty regimens – a must-have for all skin types.

Use Directions: Apply generously and evenly to face and body prior to sun exposure. Reapply frequently to maintain protection, especially after perspiring, swimming or towel drying.

Clinically and Dermatologist Tested • Non-Comedogenic • Fragrance Free • Paraben Free • Colorant Free

Drug Facts

Active Ingredients	Purpose
CCTINOXATE 7.5 % W/W	Sunscreen
OXYBENZONE 5.0 % W/W	Sunscreen
CCTISALATE 5.0 % W/W	Sunscreen
CCTOCRYLENE 5.0 % W/W	Sunscreen
AVOBENZONE 3.0 % W/W	Sunscreen

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Drug Facts (continued)

Inactive Ingredients

WATER/AQUA/EAU, NYLON-12, BUTYLENE GLYCOL, C12-15 ALKYL BENZOATE, DIMETHICONE, PENTYLENE GLYCOL, CETEARYL ALCOHOL, CAPRYLYL METHICONE, ACETYL FARNESYL CYSTEINE, AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER, ARABIDOPSIS THALIANA EXTRACT, CAPRYLYL GLYCOL, CARNOSINE, CETETH-20 PHOSPHATE, CHONDRUS CRISPUS EXTRACT, COCO-GLUCOSIDE, DICETYL PHOSPHATE, DISODIUM EDTA, ERGOTHIONEINE, HYDROXYACETOPHENONE, LECITHIN, MICROCOCCUS LYSATE, PLANKTON EXTRACT, SODIUM HYALURONATE, SODIUM PCA, TOCOPHERYL ACETATE, BHT, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM DEHYDROACETATE.

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 FACE & BODY
 Broad Spectrum
 SPF 30 Sunscreen
 Lotion
 with DNA Enzyme Complex™
 + Antioxidants

4 FL. OZ. (120 ml)

Distributed in U.S.A. by
 © Elizabeth Arden, Inc.
 New York, NY 10003
 Made in U.S.A.

7151-120-02 P16/15

FPO – UPC

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PRO TRIPLE PROTECTION FACTOR FACE AND BODY BROAD SPECTRUM SPF 30 SUNSCREEN

octinoxate, oxybenzone, octisalate, octocrylene, avobenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2076
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	.07575 g in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	.06 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	.0505 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	.0525 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	.03237 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
NYLON-12 (UNII: 446U8J075B)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
COCO GLUCOSIDE (UNII: ICS790225B)	
CARNOSINE (UNII: 8HO6PVN24W)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
ACETYL FARNESYL CYSTEINE (UNII: KK6984C8O3)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
ARABIDOPSIS THALIANA (UNII: AIBL60HQ81)	

SODIUM DEHYDROACETATE (UNII: 8W46YN971G)

ERGOTHIONEINE (UNII: BDZ3DQM98W)

HYALURONATE SODIUM (UNII: YSE9PPT4TH)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2076-1	1 in 1 BOX	02/01/2017	
1	NDC:67938-2076-2	120 mL in 1 BOTTLE; 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	02/01/2017	

Labeler - ELIZABETH ARDEN, INC (849222187)

Revised: 2/2017

ELIZABETH ARDEN, INC