

PRO TRIPLE PROTECTION FACTOR BROAD SPECTRUM SPF 50 SUNSCREEN- titanium dioxide, zinc oxide 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

Titanium Dioxide 6.1 % W/W

Zinc Oxide 5.6 % W/W

Purpose

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, CYCLOPENTASILOXANE, ISODODECANE, C12-15 ALKYL BENZOATE, CAPRYLYL METHICONE, DIMETHICONE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PENTYLENE GLYCOL, ALUMINUM HYDROXIDE, STEARIC ACID, DISTEARDIMONIUM HECTORITE, RICINOLETH-40, ETHOXYDIGLYCOL, CARNOSINE, ACETYL FARNESYL CYSTEINE, ACRYLATES/ETHYLHEXYL ACRYLATE/DIMETHICONE METHACRYLATE COPOLYMER, ALLYL CAPROATE, ARABIDOPSIS THALIANA EXTRACT, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, CHONDRUS CRISPUS EXTRACT, DIPROPYLENE GLYCOL, ERGOTHIONEINE, ETHYL DECADIENOATE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, HYDROGEN DIMETHICONE, LECITHIN, METHYLDIHYDROJASMONATE, METHYLENEDIOXYPHENYL METHYLPROPANAL, MICROCOCCUS LYSATE, PEG/PPG-18/18 DIMETHICONE, PLANKTON EXTRACT, SILICA, SODIUM HYALURONATE, SODIUM PCA, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SORBATE, SODIUM DEHYDROACETATE, IRON OXIDES (CI 77491, CI 77492, CI 77499).

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

Broad Spectrum
SPF 50 Sunscreen
Lotion

with DNA Enzyme Complex™
+ Antioxidants

**PHYSICAL SUNSCREEN
UNIVERSAL TINT**

RECOMMENDED

**SKIN
CANCER
FOUNDATION**

DAILY USE

**RECOMMENDED AS
AN EFFECTIVE
BROAD SPECTRUM
SUNSCREEN**

1.7 FL. OZ. (50 ml)

To use: Apply evenly to face and neck or as directed by your skincare professional.

Active Ingredients: TITANIUM DIOXIDE 6.1 % W/W,
ZINC OXIDE 5.6 % 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 and 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.

Other information: protect this product from excessive heat and direct sun.

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Elizabeth Arden



PRO

TRIPLE
PROTECTION
FACTOR

Broad Spectrum
SPF 50 Sunscreen
Lotion

with DNA Enzyme Complex™
+ Antioxidants

PHYSICAL SUNSCREEN
UNIVERSAL TINT



1.7 FL. OZ. (50 ml)

Principal Display Panel - Carton Label

Elizabeth Arden

PRO

TRIPLE
PROTECTION
FACTOR

Broad Spectrum

SPF 50 Sunscreen
Lotion

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**PHYSICAL SUNSCREEN
UNIVERSAL TINT**

RECOMMENDED

**SKIN
CANCER
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DAILY USE

**RECOMMENDED AS
AN EFFECTIVE
BROAD SPECTRUM
SUNSCREEN**

1.7 FL. OZ. (50 ml)

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

1. Sun Protection Factor (SPF) 50
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 universal tint perfect for all skin tones.

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

Use Directions: Apply evenly to face and neck or as directed by your skincare professional.

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

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 6.1 % W/W	Sunscreen
Zinc Oxide 5.6 % W/W	Sunscreen

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Drug Facts (continued)

Inactive Ingredients

WATER/EAU/EAU, CYCLOPENTASILOXANE, ISODODECANE, C12-15 ALKYL BENZOATE, CAPRYLYL METHICONE, DIMETHICONE, POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PENTYLENE GLYCOL, ALUMINUM HYDROXIDE, STEARIC ACID, DISTEARDIMONIUM HECTORITE, RICINOLETH-40, ETHOXYDIGLYCOL, CARBOSINE, ACETYL FRAPNESYL CYSTEINE, ACRYLATES/ETHYLHEXYL ACRYLATE, DIMETHICONE METHACRYLATE COPOLYMER, ALLYL CAPRIVATE, ARABIDOPSIS THALIANA EXTRACT, BUTYLENE GLYCOL, CAPRYLYL GLYCOL, CHONDRIUS CRISPUS EXTRACT, DIPROPYLENE GLYCOL, ERGOTHIONE, ETHYL DECADECANOATE, HDI/TRIMETHYLOL-HEXYLLACTONE CROSSPOLYMER, HYDROGEN DIMETHICONE, LECITHIN, METHYLDIHYDROXYACRYLONATE, METHYLENEDIKOPHENYL METHYLPROPANAL, MICROCOCCUS LYSATE, PEG-PPG-18/18 DIMETHICONE, PLANKTON EXTRACT, SILICA, SODIUM HYALURONATE, SODIUM PCA, TOCOPHERYL ACETATE, TRIETHOXYCAPRYLYLSILANE, CHLORPHENESIN, PHENOXYETHANOL, POTASSIUM SULFATE, SODIUM DEHYDROACETATE, IRON OXIDES (CI 77481, CI 77482, CI 77489).

Other Information

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

Questions or comments?

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Elizabeth Arden



PRO

TRIPLE PROTECTION FACTOR Broad Spectrum SPF 50 Sunscreen Lotion with DNA Enzyme Complex™ + Antioxidants

PHYSICAL SUNSCREEN UNIVERSAL TINT



1.7 FL. OZ. (50 ml)

FPO – UPC

1 86643 00302 5

PRO TRIPLE PROTECTION FACTOR BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2075
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	.25803 g in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	.31416 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPa.S) (UNII: RLA2U05Z4Q)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
RICINOLETH-40 (UNII: 6S0J4W9IQY)	
CARNOSINE (UNII: 8HO6PVN24W)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
ACETYL FARNESYL CYSTEINE (UNII: KK6984C8O3)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
METHYL DIHYDROJASMONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)	
ALLYL HEXANOATE (UNII: 3VH84A363D)	
ETHYL 2,4-DECADIENOATE, (2E,4Z)- (UNII: 79P6KS9Y5Z)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
3-(3,4-METHYLENEDIOPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	
CHONDRUS CRISPUS CARRAGEENAN (UNII: UE856F2T78)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ARABIDOPSIS THALIANA (UNII: AI3L60HQ81)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
ERGOTHIONEINE (UNII: BDZ3DQM98W)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2075-1	1 in 1 BOX	02/01/2017	
1	NDC:67938-2075-2	50 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