

**VISIBLE DIFFERENCE MULTI TARGETED BB CREAM BROAD SPECTRUM
SUNSCREEN SPF 30 SHADE 3- octinoxate, titanium dioxide, octisalate, 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.

222616

DESCRIPTION

This protective daytime BB Cream provides high protection from sun and pollution as it instantly hydrates and brightens skin. Imparts a smooth, even toned look and a soft, translucent glow.

INDICATIONS AND USAGE

Smooth onto cleansed face and throat.

WARNINGS

For external use only

OTC ACTIVE INGREDIENT

OCTINOXATE 7.5%.....Sunscreen

TITANIUM DIOXIDE 5.74% ..Sunscreen

OCTISALATE 5.0%.....Sunscreen

OXYBENZONE 3.0%.....Sunscreen

INACTIVE INGREDIENT

Water/Aqua/Eau, Butylene Glycol, Dimethicone, Caprylyl Methicone, C20-40 Pareth-3, Glycerin, Phenyl Trimethicone, Peg-8 Dimethicone, Steareth-21, Cyclopentasiloxane, Dipropylene Glycol, Silica, Stearic Acid, Adenosine, Allantoin, Alumina, Aminomethyl Propanol, Ammonium Polyacrylate, Caprylyl Glycol, Citrus Aurantium Amara (Bitter Orange) Fruit Extract, Citrus Paradisi (Grapefruit) Fruit Extract, Cnidium Officinale Root Extract, Cyclohexasiloxane, Decarboxy Carnosine HCL, Decylene Glycol, Dipotassium Glycyrrhizate, Disodium EDTA, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Seed Oil, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Lecithin, Mica, Parfum/Fragrance, Peg-10 Dimethicone, Polymethyl Methacrylate, Polysilicone-11, Polysorbate 60, Potassium Cetyl Phosphate, Potassium Hydroxide, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Steareth-2, Stearyl Alcohol, Tocopherol, Tocopheryl Acetate, VP/Eicosene Copolymer, Xanthan Gum, BHT, Sodium Ascorbate, Butylphenyl Methylpropional, Citronellol, Geraniol, Hexyl Cinnamal, Limonene, Linalool, Phenoxyethanol [May Contain/peut Contenir (+/-) Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891)]

DOSAGE AND ADMINISTRATION

Smooth onto face and throat

OTC - KEEP OUT OF REACH OF CHILDREN
Keep out of reach of children.

OTC - PURPOSE

Provides SPF 30 sun protection

OTC - WHEN USING

Keep out of eyes. Rinse with water to remove

DO NOT USE

Do not use

on damaged or broken skin

STOP USE

If rash occurs

This protective daytime BB Cream provides high protection from sun and pollution as it instantly hydrates and brightens skin. Imparts a smooth, even toned look and a soft, translucent glow. Achieve balanced, healthier-looking skin with improved tone and texture with continued use. Suitable for all skin types. In 3 skin enhancing shades.
To use: Smooth onto cleansed face and throat.

Drug Facts
Active Ingredients...Purpose OCTINOXATE 7.5%.....Sunscreen TITANIUM DIOXIDE 5.74% ..Sunscreen OCTISALATE 5.0%.....Sunscreen OXYBENZONE 3.0%.....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
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 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, Dimethicone, Caprylyl Methicone, C20-40 Pareth-3, Glycerin, Phenyl Trimethicone, Peg-8 Dimethicone, Steareth-21, Cyclopentasiloxane, Dipropylene Glycol, Silica, Stearic Acid, Adenosine, Allantoin, Alumina, Aminomethyl Propanol, Ammonium Polyacrylate, Caprylyl Glycol, Citrus Aurantium Amara (Bitter Orange) Fruit Extract, Citrus Paradisi (Grapefruit) Fruit Extract,

Visible Difference
Multi-Targeted
BB Cream
Broad Spectrum
Sunscreen SPF 30

Elizabeth Arden
NEW YORK

NET WT.
1 OZ.
34 g

Drug Facts (continued) Cnidium Officinale Root Extract, Cyclohexasiloxane, Decarboxy Carnosine HCL, Decylene Glycol, Dipotassium Glycyrrhizate, Disodium EDTA, Glycyrrhiza Glabra (Licorice) Root Extract, Helianthus Annuus (Sunflower) Seed Oil, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Isohexadecane, Lecithin, Mica, Parfum/Fragrance, Peg-10 Dimethicone, Polymethyl Methacrylate, Polysilicone-11, Polysorbate 60, Potassium Cetyl Phosphate, Potassium Hydroxide, Sodium Ascorbyl Phosphate, Sodium Hyaluronate, Steareth-2, Stearyl Alcohol, Tocopherol, Tocopheryl Acetate, VP/Eicosene Copolymer, Xanthan Gum, BHT, Sodium Ascorbate, Butylphenyl Methylpropional, Citronellol, Geraniol, Hexyl Cinnamal, Limonene, Linalool, Phenoxyethanol [May Contain/peut Contenir (+/-) Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891)]
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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octinoxate, titanium dioxide, octisalate, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-2004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.55 g in 34 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.95 g in 34 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.7 g in 34 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.02 g in 34 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
C20-40 PARETH-3 (UNII: 68103A23TQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG-8 DIMETHICONE (UNII: GIA7T764OD)	
STEARETH-21 (UNII: 53J3F32P58)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ADENOSINE (UNII: K72T3FS567)	
ALLANTOIN (UNII: 344S277G0Z)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DECYLENE GLYCOL (UNII: S57M60MI88)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPAS AT 1%) (UNII: 86FQE96TZ4)	
ISOHEXADECANE (UNII: 918X10UF1E)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MICA (UNII: V8A1AW0880)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM ASCORBATE (UNII: S033EH8359)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
GERANIOL (UNII: L837108USY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Product Characteristics

Color	BROWN (LIGHT BEIGE)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-2004-1	1 in 1 BOX		
1	NDC:67938-2004-2	34 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/17/2013	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 7/2013

Elizabeth Arden, Inc