

VISIBLE DIFFERENCE SKIN BALANCING SUNSCREEN SPF 15- octinoxate and oxybenzone 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.

BB1000

DESCRIPTION

This lightweight, oil-free lotion for combination skin leaves skin feeling healthy and balanced with a radiant appearance.

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. Children under 6 months: Ask a doctor.

WARNINGS

Warnings:

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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 6.0 %, Oxybenzone 3.0 %

INACTIVE INGREDIENT

Inactive Ingredients: Water/Aqua/Eau, Dimethicone, Isononyl Isononanoate, Glycerin, Tridecyl Salicylate, Steareth-21, Isostearic Acid, Octyldodecyl Neopentanoate, Aluminum Starch Octenylsuccinate, Salvia Officinalis (Sage) Leaf Extract, Hydrolyzed Glycosaminoglycans, Sodium Hyaluronate, Sodium Lactate, Retinyl Linoleate, Tetrahexyldecyl Ascorbate, Tocopherol, Glyceryl Stearate, Propylene Glycol, Panthenol, C12-20 Acid PEG-8 Ester, Cetyl Alcohol, PEG-100 Stearate, Trilaureth-4 Phosphate, Steareth-2 Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ethylene/VA Copolymer, Sclerotium Gum, Triethanolamine, BHT, Disodium EDTA, Parfum/Fragrance, Benxyl Salicylate, Butylphenyl Methylpropional, Citronellol, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Limonene, Linalool, DMDM Hydantoin, Methylparaben, Phenoxyethanol, Propylparaben.

DOSAGE & ADMINISTRATION

Smooth on to face.

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.

OTC - WHEN USING

Keep out of eyes.

Visible Difference
Skin Balancing Lotion
Sunscreen SPF 15

 Elizabeth Arden
NEW YORK

This lightweight, oil-free lotion for combination skin leaves skin feeling healthy and balanced with a radiant appearance.

To use: Smooth onto cleansed face and throat.

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New York, NY 10003
elizabetharden.com

Sample. Not for sale.

Made in U.S.A.

No. 7376MP1200

Active Ingredients	Purpose
OCTINOXATE 6.0%	Sunscreen
OXYBENZONE 3.0%	Sunscreen

Drug Facts (continued)

Uses

- Helps prevent sunburn

Warnings

- Skin Cancer/Skin Aging Alert: Spending time in the sun

Drug Facts (continued)

increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

- For external use only
- Do not use on damaged or broken skin

Drug Facts (continued)

- 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
- Children under 6 months: Ask a doctor.

Drug Facts (continued)

Inactive Ingredients

WATER/AQUA/EAU, DIMETHICONE, ISONONYL ISONONANOATE, GLYCERIN, TRIDECYL SALICYLATE, STEARETH-21, ISOSTEARIC ACID, OCTYLDODECYL NEOPENTANOATE, ALUMINUM STARCH

Drug Facts (continued)

OCTENYLSUCCINATE, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, HYDROLYZED GLYCOSAMINOGLYCANS, SODIUM HYALURONATE, SODIUM LACTATE, RETINYL LINOLEATE, TETRAHEXYLDECYL ASCORBATE, TOCOPHEROL, GLYCERYL STEARATE, PROPYLENE

Drug Facts (continued)

GLYCOL, PANTHENOL, C12-20 ACID PEG-8 ESTER, CETYL ALCOHOL, PEG-100 STEARATE, TRILAURETH-4 PHOSPHATE, STEARETH-2, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, ETHYLENE/VA COPOLYMER, SCLEROTIUM GUM, TRIETHANOLAMINE,

Drug Facts (continued)

BHT, DISODIUM EDTA, PARFUM/FRAGRANCE, BENZYL SALICYLATE, BUTYLPHENYL METHYLPROPIONAL, CITRONELLOL, HYDROXYISOHXYL 3-CYCLOHEXENE CARBOXALDEHYDE, LIMONENE, LINALOOL, DMDM HYDANTOIN, METHYLPARABEN, PHENOXYETHANOL,

Drug Facts (continued)

PROPYLPARABEN.

Other Information

- Protect this product from excessive heat and direct sun

Drug Facts (continued)

Questions or comments?
■ Call toll free 1-800-326-7337

Visible Difference
Skin Balancing Lotion
Sunscreen SPF 15

 Elizabeth Arden
NEW YORK

combination

To use: Smooth onto cleansed face and throat.

ACTIVE INGREDIENTS: OCTINOXATE, 6.0 %, OXYBENZONE, 3.0 %

USES: Helps prevent sunburn.

WARNINGS: SKIN CANCER/SKIN AGING ALERT: SPENDING TIME IN THE SUN INCREASES YOUR RISK OF SKIN CANCER AND EARLY SKIN AGING. THIS PRODUCT HAS BEEN SHOWN ONLY TO PREVENT SUNBURN, NOT SKIN CANCER OR EARLY SKIN AGING. **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. 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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VISIBLE DIFFERENCE SKIN BALANCING SUNSCREEN SPF 15

octinoxate and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	60 mg in 50 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	30 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIDECYL SALICYLATE (UNII: AZQ08K38Z1)	
STEARETH-21 (UNII: 53J3F32P58)	
ISO STEARIC ACID (UNII: X33R8U0062)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
SAGE (UNII: 065C5D077J)	
HYDROLYZED GLYCOSAMINOGLYCANS (BOVINE; 50000 MW) (UNII: 997385V0VV)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
RETINYL LINOLEATE (UNII: 61911N8D6W)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PANTHENOL (UNII: WV9CM0O67Z)	
PEG-100 STEARATE (UNII: YD01N1999R)	
TRILAURETH-4 PHOSPHATE (UNII: M96W2OLL2V)	
STEARETH-2 (UNII: V56DFE46J5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE (UNII: QUE43B9Z2Q)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE49ZZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1000-1	1 in 1 CARTON		
1	NDC:67938-1000-2	50 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/16/2011	

Labeler - Elizabeth Arden, Inc (849222187)

