

FLAWLESS FINISH BARE PERFECTION MAKEUP SPF 8 CAMELLIA- octinoxate 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.

BC0834

DESCRIPTION

For normal skin. Medium coverage. Natural finish. This oil free liquid makeup gives skin a firmer look and reflects light to soften fine lines. SPF 8 provides sun protection. Clinically, dermatologist and allergy tested.

INDICATIONS AND USAGE

To Use: Smooth on to face before sun exposure.

WARNINGS

Warning: For external use only. Keep out of eyes. Stop use and see a doctor if rash or irritation develops and lasts. Keep out of reach of children.

OTC - ACTIVE INGREDIENT

Active Ingredient: Octinoxate 4.0% w/w.

INACTIVE INGREDIENT

Other Ingredients: Water/Aqua/Eau, Isostearyl Palmitate, C12-15 Alkyl Benzoate, Butylene Glycol, Dimethicone, Oleic Acid, Glycerin, C12-20 Acid PEG-8 Ester, Polysorbate 40, Triethanolamine, Magnesium Aluminum Silicate, Dimethicone Copolyol, Phenyl Trimethicone, Sodium Hyaluronate, Retinyl Linoleate, Tocopherol, Glyceryl Stearate SE, Sucrose Laurate, Trehalose, Lecithin, Phospholipids, Tridecyl Salicylate, Decyl Glucoside, PEG-40 Stearate, Sorbitan Palmitate, Sorbitan Stearate, Behenyl Alcohol, Carbomer, Xanthan Gum, Disodium EDTA, Kaolin, Silica, Cyclopentasiloxane, Dimethiconol, Parfum/Fragrance, Butylphenyl Methylpropional, Hydroxycitronellal, Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde, Limonene, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Iron Oxides (CI77491, CI 77492, CI 77499), Titanium Dioxide (CI 77891).

DOSAGE & ADMINISTRATION

Smooth on to face.

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

OTC - PURPOSE

SPF 8 provides sun protection.

OTC - WHEN USING

Keep out of eyes.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FLAWLESS FINISH BARE PERFECTION MAKEUP SPF 8 CAMELLIA

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-0834
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.1988 mL in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
OLEIC ACID (UNII: 2UMI9U37CP)	

GLYCERIN (UNII: PDC6A3C0OX)
POLYSORBATE 40 (UNII: ST11B5A2X)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
TROLAMINE (UNII: 9O3K93S3TK)
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)
KAOLIN (UNII: 24H4NWX5CO)
XANTHAN GUM (UNII: TTV12P4NEE)
PHENOXYETHANOL (UNII: HE492ZZ3T)
SUCROSE LAURATE (UNII: 05Q7CD0E49)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
METHYL PARABEN (UNII: A2I8C7HI9T)
DOCOSANOL (UNII: 9G1OE216XY)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)

Product Characteristics

Color	PINK (Camellia)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-0834-1	1 in 1 BOX		
1	NDC:67938-0834-2	30 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/06/2011	

Labeler - Elizabeth Arden, Inc (849222187)