

**INTERVENE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SOFT CREAM-
octinoxate 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.

BC1077

DESCRIPTION

For normal skin. Medium/full coverage. Soft natural finish. This innovative liquid makeup with Biodormin technology helps delay the appearance of new lines and wrinkles as it firms the look of skin. Micro-mineral pigment technology smooths imperfections, evens out skin tone and creates a soft natural finish that lasts all day.

INDICATIONS AND USAGE

To Use: Smooth on to face.

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.

WARNINGS

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.

OTC - ACTIVE INGREDIENT

Active Ingredient: Octinoxate 5.0%.

INACTIVE INGREDIENT

Other Ingredients: Cyclopentasiloxane, Water/Aqua/Eau, Isododecane, Butylene Glycol, Talc, Mica, Polymethyl Methacrylate, Silica Silylate, Sorbitan Tristearate, PEG/PPG-18/18 Dimethicone, Silica, Trimethylsiloxysilicate, Palmitoyl Tetrapeptide-7, Narcissus Tazetta Bulb Extract, Trifolium Pratense (Clover) Flower Extract, Ascorbyl Palmitate, Tocopherol, Lecithin, Glycerin, Hydrolyzed Soy Protein, Laureth-4, Laureth-7, Steareth-20, Distearidimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Propylene Carbonate, BHT, Sodium Chloride, Dimethicone, Dimethiconol, Fragrance/Parfum, Butylparaben, Ethylparaben, Isobutylparaben, Methylparaben, Phenoxyethanol, Propylparaben, Sodium Dehydroacetate, Iron Oxides (CI 77491, CI 77492, CI 77499), Titanium Dioxide (CI77891).

DOSAGE & ADMINISTRATION

Smooth on to face.

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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

*For normal skin.
•Medium/full coverage. Soft natural finish.
•This innovative liquid makeup with Bioformer™ technology helps delay the appearance of new lines and wrinkles as it firms the look of skin. Micro-mixed pigment technology smooths imperfections, evens out skin tone and creates a soft natural finish that lasts all day.
Provides Broad Spectrum Sunscreen SPF 15 protection.
To use: Smooth onto face.
Clinically, dermatologist and allergy tested.

Active Ingredient	Purpose
OCTINOXATE 5.0%	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.

Directions For Sunscreen Use:

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - at least every 2 hours
- Sun Protection Measures.

Drug Facts (continued)

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

CYCLOPENTASILOXAN E, WATER/AQUA/EAU, ISODODECANE, BUTYLENE GLYCOL, TALC, MICA, POLYMETHYL METHACRYLATE, SILICA Silylate, SORBITAN TRISTEARATE, PEG/PPG-18/18 DIMETHICONE, SILICA, TRIMETHYLSILOXYSILICATE, PALMITOYL TETRAPEPTIDE-7, NARCISSUS TAZETTA BULB EXTRACT, TRIFOLIUM PRATENSE (CLOVER) FLOWER EXTRACT, ASCORBYL PALMITATE, TOCOPHEROL.



Elizabeth Arden
NEW YORK

Intervene
Makeup
Broad Spectrum
Sunscreen SPF 15

Drug Facts (continued)

LECITHIN, GLYCERIN, HYDROLYZED SOY PROTEIN, LAURETH-4, LAURETH-7, STEARETH-20, DISTEARDIMONIUM HECTORITE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PROPYLENE CARBONATE, BHT, SODIUM CHLORIDE, DIMETHICONE, DIMETHICONOL, FRAGRANCE/PARFUM, BUTYLPARABEN, ETHYLPARABEN, ISOBUTYLPARABEN, METHYLPARABEN, PHENOXYETHANOL, PROPYLPARABEN, SODIUM DEHYDROACETATE, IRON OXIDES (CI 77491, CI 77492, CI 77499), TITANIUM DIOXIDE (CI 77891).

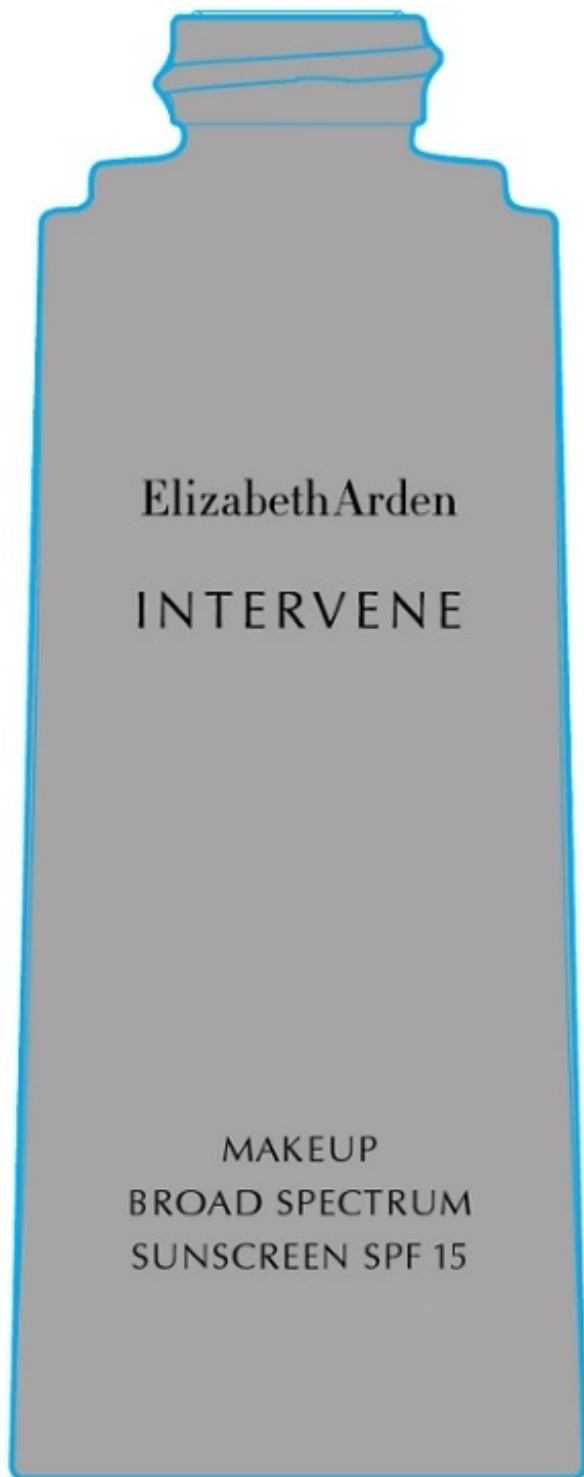
Other Information

- Protect this product from excessive heat and direct sun

Questions or comments?

- Call toll free 1-800-326-7337

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elizabetharden.com



INTERVENE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SOFT CREAM

octinoxate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67938-1077
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.5 g in 30 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
TALC (UNII: 7SEV7J4R1U)	
SORBITAN TRISTEARATE (UNII: 6LUM696811)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
LAURETH-7 (UNII: Z95S6G8201)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
BUTYL PARABEN (UNII: 3QP1I3FV8)	
NARCISSUS TAZETTA BULB (UNII: K17762966S)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
ISOBUTYL PARABEN (UNII: 0QQJ25X58G)	
LAURETH-4 (UNII: 6HQ855798J)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
STEARETH-20 (UNII: L0Q8IK9E08)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIFOLIUM PRATENSE FLOWER (UNII: 4JS0838828)	
PALMITOYL TETRAPEPTIDE-7 (UNII: Q41S464P1R)	

Product Characteristics

Color	PINK (Soft Cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67938-1077-1	1 in 1 BOX		
1	NDC:67938-1077-2	30 g in 1 BOTTLE, PUMP		
2	NDC:67938-1077-3	25000 g in 1 PAIL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/06/2010	

Labeler - Elizabeth Arden, Inc (849222187)

Revised: 7/2013

Elizabeth Arden, Inc