

**INTERVENE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SOFT COGNAC-  
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.*

-----

**BC1084**

**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

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.



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).

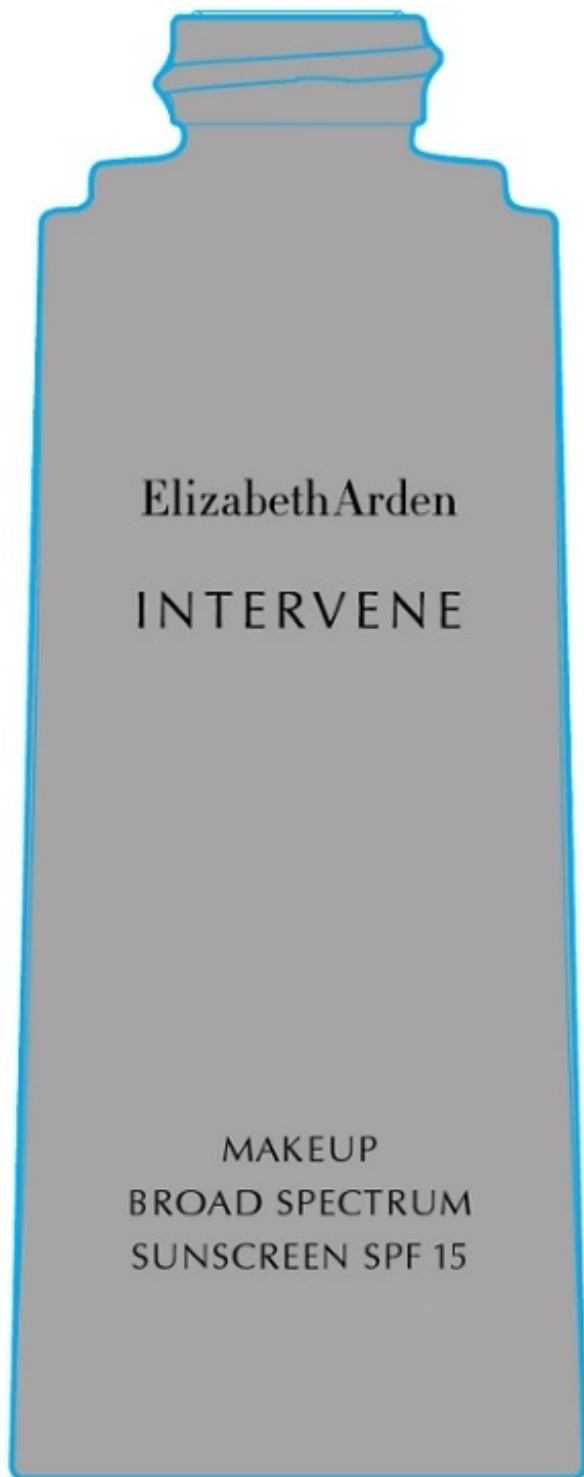
### Other Information

- Protect this product from excessive heat and direct sun

### Questions or comments?

- Call toll free 1-800-326-7337

Distributed in U.S.A. by  
©Elizabeth Arden, Inc.  
New York, NY 10003  
Made in Italy  
elizabetharden.com



**INTERVENE MAKEUP BROAD SPECTRUM SUNSCREEN SPF 15 SOFT COGNAC**

octinoxate cream

**Product Information**

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:67938-1084 |
| <b>Route of Administration</b> | 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: 3QP1IU3FV8)             |          |
| 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    | BROWN (Soft Cognac) | Score        |  |
| Shape    |                     | Size         |  |
| Flavor   |                     | Imprint Code |  |
| Contains |                     |              |  |

**Packaging**

| # | Item Code        | Package Description    | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------|----------------------|--------------------|
| 1 | NDC:67938-1084-1 | 1 in 1 BOX             |                      |                    |
| 1 | NDC:67938-1084-2 | 30 g in 1 BOTTLE, PUMP |                      |                    |
| 2 | NDC:67938-1084-3 | 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