

**ESIKA NATURAL CARE- octinoxate and oxybenzone cream**  
**Ventura Corporation Ltd**

*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.*

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**ésika**  
**natural care**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
OCTINOXATE 7.5%	Sunscreen
OXYBENZONE 4.5%	Sunscreen

**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 help 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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

- Apply liberally and evenly 15 minutes before sun exposure.
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

**Other information**

- Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients**

AQUA (WATER), GLYCERYL STEARATE, CYCLOPENTASILOXANE, C12-15 ALKYL BENZOATE, PEG-100 STEARATE, CETYL ALCOHOL, DICAPRYLYL CARBONATE, PROPYLENE GLYCOL, GLYCERIN, PHENOXYETHANOL, CYCLOHEXASILOXANE, DIMETHICONE, METHYLPARABEN, CI 77891 (TITANIUM DIOXIDE ), PAPAIN,

TRIETHANOLAMINE, PROPYL PARABEN, ACRYLATES/C10-30 ALKYL ACRYLATE  
CROSSPOLYMER, SODIUM LACTATE, CASTORYL MALEATE, PARFUM (FRAGRANCE),  
BUTYLENE GLYCOL, TETRASODIUM EDTA, CALCIUM PANTOTHENATE,  
ARCTOSTAPHYLOS UVA URSI LEAF EXTRACT, XANTHAN GUM, BUTYL PARABEN,  
ETHYL PARABEN, CAPRYLYL GLYCOL, ROSA MOSCHATA SEED OIL, UREA, MAGNESIUM  
LACTATE, ETHYLHEXYLGLYCERIN, POTASSIUM LACTATE, ISOBUTYL PARABEN,  
ALANINE, MAGNESIUM CHLORIDE, PROLINE, SERINE, SODIUM CITRATE, MOTHER OF  
PEARL EXTRACT.

Dist. by Ventura Corporation, Ltd. San  
Juan, Puerto Rico 00926.

**PRINCIPAL DISPLAY PANEL - 60 g Bottle Carton**

**naturalcare**

rosa mosqueta  
& concha de nácar

crema aclaradora facial FPS 15

60 g e (2.1 oz.)

**ésika**

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### **Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate (7.5%), Oxybenzone (4.5%).....	Sunscreen

**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 help prevent sunburn, not skin cancer or early skin aging.

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**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 swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ■ Apply liberally and evenly 15 minutes before sun exposure. ■ Reapply at least every 2 hour. ▶

### **Drug Facts (continued)**

- Use a water resistant sunscreen if swimming or sweating.
- Children under 6 months of age: Ask a doctor

**Other information** ■ Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients** aqua (water), glyceryl stearate, cyclopentasiloxane, c12-15 alkyl benzoate, peg-100 stearate, cetyl alcohol, dicaprylyl carbonate, propylene glycol, glycerin, phenoxyethanol, cyclohexasiloxane, dimethicone, methylparaben, ci 77891 (titanium dioxide ), papain, triethanolamine, propylparaben, acrylates/c10-30 alkyl acrylate crosspolymer, sodium lactate, castoryl maleate, parfum (fragrance), butylene glycol, tetrasodium edta, calcium pantothenate, arctostaphylos uva ursi leaf extract, xanthan gum, butylparaben, ethylparaben, caprylyl glycol, rosa moschata seed oil, urea, magnesium lactate, ethylhexylglycerin, potassium lactate, isobutylparaben, alanine, magnesium chloride, proline, serine, sodium citrate, mother of pearl extract.

P.R.: Dist. by Ventura Corporation, Ltd, San Juan, Puerto Rico 00926, Made in Colombia.

**ESIKA NATURAL CARE**

octinoxate and oxybenzone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-152
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.045 g in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THF5PC10R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PAPAIN</b> (UNII: A236A06Y32)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>CALCIUM PANTOTHENATE</b> (UNII: 568ET80C3D)	
<b>ARCTOSTAPHYLOS UVA-URSIFOLIUM LEAF</b> (UNII: 3M5V3D1X36)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BUTYL PARABEN</b> (UNII: 3QPI1U3FV8)	
<b>ETHYL PARABEN</b> (UNII: 14255EXE39)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>ROSA MOSCHATA SEED OIL</b> (UNII: T031ZE559T)	
<b>UREA</b> (UNII: 8W8T17847W)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>POTASSIUM LACTATE</b> (UNII: 87V1KMK4QV)	
<b>ISOBUTYL PARABEN</b> (UNII: 0QQJ25X58G)	
<b>ALANINE</b> (UNII: OF5P57N2ZX)	
<b>MAGNESIUM CHLORIDE</b> (UNII: 02F3473H9O)	
<b>PROLINE</b> (UNII: 9DLQ4CIU6V)	
<b>SERINE</b> (UNII: 452VLY9402)	

SODIUM CITRATE (UNI: 1Q73Q2JULR)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-152-01	1 in 1 CARTON		
1		60 g in 1 BOTTLE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	01/24/2012	

**Labeler** - Ventura Corporation Ltd (602751344)

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-152)

Revised: 8/2013

Ventura Corporation Ltd