

**BRIGHTENING AND MOISTURIZING FACIAL SPF 30- avobenzone, ensulizole, octisalate, octocrylene, and oxybenzone lotion**

**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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**Brightening and moisturizing facial lotion SPF 30**

**Drug Facts**

<b>Active Ingredients</b>	<b>Purpose</b>
AVOBENZONE 3.00%	Sunscreen
ENSULIZOLE 3.00 %	Sunscreen
OCTISALATE 5.00 %	Sunscreen
OCTOCRYLENE 5.00 %	Sunscreen
OXYBENZONE 6.00 %	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**

WATER, DICAPRYLYL CARBONATE, CETEARYL ALCOHOL, PHENETHYL BENZOATE, TRIETHANOLAMINE, CYCLOPENTASILOXANE, PROPYLENE GLYCOL, METHYL

METHACRYLATE CROSSPOLYMER, SORBITAN STEARATE, TRIETHYLHEXANOIN, POTASSIUM CETYL PHOSPHATE, PHENOXYETHANOL, DIMETHICONE, STEARYL DIMETHICONE, CETEARETH-20, XANTHAN GUM, CETYL ALCOHOL, GLYCERYL STEARATE, CHLORPHENESIN, FRAGRANCE, VIGNA ACONITIFOLIA SEED EXTRACT, DIMETHYLMETHOXY CHROMANYL PALMITATE, PEG-75 STEARATE, SODIUM COCOYL GLUTAMATE, TETRASODIUM EDTA, CETETH-20, STEARETH-20, BUTYLPARABEN, SORBIC ACID, METHYLPARABEN, ALPHA-ISOMETHYL IONONE, HYDROXYCITRONELLAL, d-LIMONENE, LINALOOL, BENZYL SALICYLATE, CITRONELLOL.

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

**PRINCIPAL DISPLAY PANEL - 30 ml Bottle Box**

**L'BEL**

DERMO CLARITÉ

brightening and moisturizing **facial  
lotion SPF 30**

30 ml e (1 fl.oz.)

# L'BEL

DERMO CLARITÉ

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Avobenzone 3.0%,	Sunscreen
Ensulizole 3.0%,	Sunscreen
Octisalate 5.0%,	Sunscreen
Octocrylene 5.0%,	Sunscreen
Oxybenzone 6.0%	Sunscreen

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**Inactive ingredients:** water, dicaprylyl carbonate, cetearyl alcohol, phenethyl benzoate, triethanolamine, cyclopentasiloxane, propylene glycol, methyl methacrylate crosspolymer, sorbitan stearate, triethylhexanoin, potassium cetyl phosphate, phenoxyethanol, dimethicone, stearyl dimethicone, cetareth-20, xanthan gum, cetyl alcohol, glyceryl stearate, chlorphenesin, fragrance, vigna aconitifolia seed extract, dimethylmethoxy chromanyl palmitate, peg-75 stearate, sodium cocoyl glutamate, tetrasodium edta, ceteth-20, steareth-20, butylparaben, sorbic acid, methylparaben, alpha-isomethyl ionone, hydroxycitronellal, d-limonene, linalool, benzyl salicylate, citronellol.

brightening and moisturizing facial lotion SPF 30  
loción facial iluminadora hidratante con FPS 30

U.S.A.: Dist. by Ventura Int. Ltd., DBA Solcorp  
USA: Miami, FL 33128 Made in Colombia  
PUERTO RICO: Dist. by Ventura Corp. Ltd.,  
San Juan, Puerto Rico 00926. Made in  
Colombia  
Formulated in France

30 ml e (1 fl.oz.)

**BRIGHTENING AND MOISTURIZING FACIAL SPF 30**  
avobenzone, ensulizole, octisalate, octocrylene, and oxybenzone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-993
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzene</b> (UNII: G63QQF2NOX) (Avobenzene - UNII:G63QQF2NOX)	Avobenzene	0.03 g in 1 mL
<b>Ensulizole</b> (UNII: 9YQ9DIIW42) (Ensulizole - UNII:9YQ9DIIW42)	Ensulizole	0.03 g in 1 mL
<b>Octisalate</b> (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 mL
<b>Octocrylene</b> (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.05 g in 1 mL
<b>Oxybenzone</b> (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.06 g in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PC10R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>STEARYL DIMETHICONE (400 MPAS AT 50C)</b> (UNII: R327X197HY)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>MOTH BEAN</b> (UNII: H7938ON8E5)	
<b>DIMETHYLMETHOXY CHROMANYL PALMITATE</b> (UNII: 5G222ZDK7U)	
<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)	
<b>SODIUM COCOYL GLUTAMATE</b> (UNII: BMT4RCZ3HG)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>BUTYLPARABEN</b> (UNII: 3QPI1U3FV8)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>HYDROXYCITRONELLAL</b> (UNII: 8SQ0VA4YUR)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MKN9TU)	
<b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-993-02	1 in 1 BOX	09/26/2016	
1	NDC:13537-993-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/26/2016	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-993)

Revised: 9/2016

Ventura Corporation LTD