

**LBEL ESSENTIAL DEEP MOISTURIZING AND OXYGENATING SPF 20 NORMAL TO OILY SKIN- avobenzone, octinoxate, octisalate, and octocrylene 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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**L'BEL ESSENTIAL deep moisturizing and oxygenating lotion SPF 20 normal to oily skin**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
AVOBENZONE (3.00 %)	Sunscreen
OCTINOXATE (3.00 %)	Sunscreen
OCTISALATE (5.00 %)	Sunscreen
OCTOCRYLENE (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, GLYCERIN, BUTYLENE GLYCOL, ALUMINUM STARCH OCTENYLSUCCINATE, C12-15 ALKYL BENZOATE, CYCLOHEXASILOXANE, CETEARYL ALCOHOL, DIMETHICONE, TOCOPHERYL ACETATE, GLYCERYL STEARATE, PHENOXYETHANOL,

ETHYLHEXYLGLYCERIN, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, CETYL ALCOHOL, CETEARETH-20, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, FRAGRANCE, XANTHAN GUM, PEG-75 STEARATE, ENANTIA CHLORANTHA BARK EXTRACT, METHYLPROPANEDIOL, BHT, TETRASODIUM EDTA, SACCHAROMYCES LYSATE, CETETH-20, STEARETH-20, SILANEDIOL SALICYLATE, SODIUM HYDROXIDE, TROMETHAMINE, METHYL PERFLUOROBUTYL ETHER, ISODODECANE, DISODIUM SUCCINATE, SILICA, GLUTAMIC ACID, GLYCINE, THREONINE, VALINE , POLYSILICONE-11, OLEANOLIC ACID, BLUE 1, DECYL GLUCOSIDE.

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

**PRINCIPAL DISPLAY PANEL - 50 mL Tube Box**

**L'BEL**

ESSENTIAL

deep moisturizing  
and oxygenating

**lotion** SPF 20

*normal to oily skin*

50 ml e (1.6 fl.oz.)

www.lbel.com

**L'BEL**

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PUERTO RICO: Dist. by Ventura Corp. Ltd., San Juan, Puerto Rico 00926. Made in Colombia.

Formulado en Francia/Fabricado en Colombia  
Formulated in France/Made in Colombia

**ESSENTIAL**

loción facial  
alta hidratación efecto  
oxigenador FPS 20  
piel normal a grasa

deep moisturizing  
and oxygenating  
lotion SPF 20  
normal to oily skin

50 ml e (1.6 fl.oz.)

**Drug Facts (continued)**

**Other Information**

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

**Inactive Ingredients**

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# LBEL ESSENTIAL DEEP MOISTURIZING AND OXYGENATING SPF 20 NORMAL TO OILY SKIN

avobenzone, octinoxate, octisalate, and octocrylene lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13537-637
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Avobenzone</b> (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 mL
<b>Octinoxate</b> (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	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	0.06 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0K00R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128MIS)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>PEG-75 STEARATE</b> (UNII: OT38R0N74H)	
<b>ANNICKIA CHLORANTHA BARK</b> (UNII: H70115MP4A)	
<b>METHYLPROPANEDIOL</b> (UNII: N8F53B3R4R)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>SACCHAROMYCES LYSATE</b> (UNII: R85W246Z1C)	
<b>CETETH-20</b> (UNII: I835H2IHHX)	
<b>STEARETH-20</b> (UNII: L0Q8IK9E08)	
<b>SILANEDIOL SALICYLATE</b> (UNII: C054DF30K0)	

<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>TROMETHAMINE</b> (UNII: 023C2WHX2V)
<b>METHYL PERFLUOROBUTYL ETHER</b> (UNII: H637A50B7U)
<b>ISODODECANE</b> (UNII: A8289P68Y2)
<b>SODIUM SUCCINATE ANHYDROUS</b> (UNII: V8ZGC8ISR3)
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>GLUTAMIC ACID</b> (UNII: 3KX376GY7L)
<b>GLYCINE</b> (UNII: TE7660XO1C)
<b>THREONINE</b> (UNII: 2ZD004190S)
<b>VALINE</b> (UNII: HG18B9YRS7)
<b>OLEANOLIC ACID</b> (UNII: 6SMK8R7TGJ)
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-637-02	1 in 1 BOX		
1	NDC:13537-637-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:13537-637-04	1 in 1 BOX		
2	NDC:13537-637-03	5 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:13537-637-06	1 in 1 CARTON		
3	NDC:13537-637-05	1 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:13537-637-08	1 in 1 CARTON		
4	NDC:13537-637-07	0.25 mL in 1 PACKET; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/09/2015	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-637)

Revised: 3/2015

Ventura Corporation LTD