

**L'BEL ESSENTIAL MOISTURIZING AND OXYGENATING SPF 20 NORMAL TO DRY SKIN-
avobenzone, octinoxate, octisalate, and octocrylene 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.

L'BEL ESSENTIAL moisturizing and oxygenating cream SPF 20 normal to dry skin

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
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, C12-15 ALKYL BENZOATE, GLYCERYL STEARATE, DIMETHICONE, CYCLOHEXASILOXANE, TAPIOCA STARCH, ISOPROPYL

PALMITATE, TOCOPHERYL ACETATE, IMPERATA CYLINDRICA ROOT EXTRACT, PHENOXYETHANOL, ETHYLHEXYLGLYCERIN, CETYL ALCOHOL, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, XANTHAN GUM, PEG-75 STEARATE, CETEARYL ISONONANOATE, FRAGRANCE, DIMETHICONOL, METHYLPROPANEDIOL, CETEARETH-20, CETEARYL ALCOHOL, BHT, PEG- 8, TETRASODIUM EDTA, CETETH-20, SACCHAROMYCES LYSATE, STEARETH-20, SILANEDIOL SALICYLATE , SODIUM HYDROXIDE, TROMETHAMINE, METHYL PERFLUOROBUTYL ETHER, CARBOMER, ISODODECANE, CETEARETH-12, CETYL PALMITATE, DISODIUM SUCCINATE, GLUTAMIC ACID, GLYCINE, THREONINE, VALINE, POLYS ILICONE-11, DECYL GLUCOSIDE.

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

PRINCIPAL DISPLAY PANEL - 50 g Tube Box

L'BEL

ESSENTIAL

deep moisturizing
and oxygenating
cream SPF 20
normal to dry skin

Net Weight 1.7 oz (50g)

www.lbel.com

L'BEL

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Drug Facts (continued)

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ESSENTIAL

crema facial
alta hidratación efecto
oxigenador FPS 20
piel normal a seca

deep moisturizing
and oxygenating
cream SPF 20
normal to dry skin

Net Weight 1.7 oz (50g)

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

LBEL ESSENTIAL MOISTURIZING AND OXYGENATING SPF 20 NORMAL TO DRY SKIN

avobenzone, octinoxate, octisalate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-641
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	0.03 g in 1 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.03 g in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.05 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.06 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
IMPERATA CYLINDRICA ROOT (UNII: VYT2JA85NH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
CETEARYL ISONONANOATE (UNII: P5O01U99N)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
EDETATE SODIUM (UNII: MP1J8420LU)	
CETETH-20 (UNII: I835H2IHHX)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	

STEARETH-20 (UNII: L0Q8IK9E08)
SILANEDIOL SALICYLATE (UNII: C054DF30K0)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
TROMETHAMINE (UNII: 023C2WHX2V)
METHYL PERFLUOROBUTYL ETHER (UNII: H637A50B7U)
ISODODECANE (UNII: A8289P68Y2)
CETEARETH-12 (UNII: 7V4MR24V5P)
CETYL PALMITATE (UNII: 5ZA2S6B08X)
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)
GLUTAMIC ACID (UNII: 3KX376GY7L)
GLYCINE (UNII: TE7660XO1C)
THREONINE (UNII: 2ZD004190S)
VALINE (UNII: HG18B9YRS7)
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-641-02	1 in 1 BOX		
1	NDC:13537-641-01	50 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:13537-641-04	1 in 1 BOX		
2	NDC:13537-641-03	5 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:13537-641-06	1 in 1 CARTON		
3	NDC:13537-641-05	1 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:13537-641-08	1 in 1 CARTON		
4	NDC:13537-641-07	0.25 g 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(13537-641)