

L'BEL 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.

L'BEL ESSENTIAL Deep moisturizing and oxygenating lotion SPF 20 normal to oily skin

Drug Facts

Active Ingredients	Purpose
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, LINALOOL, d-LIMONENE, HEXYL CINNAMAL, BUTYLPHENYL METHYLPROPIONAL, ALPHA-ISOMETHYL IONONE

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

PRINCIPAL DISPLAY PANEL - 5 ml Tube Box

L'BEL

ESSENTIAL

deep moisturizing
and oxygenating
lotion SPF 20
normal to oily skin

5 ml e (0.16 fl.oz.)

www.lbel.com



L'BEL

ESSENTIAL

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

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Drug Facts (continued)

acrylate/c10-30 alkyl acrylate copolymer, fragrance, xanthan gum, peg-75 stearate, eurylia chlorantha bark extract, methylpropenediol, bht, tetrasodium edta, saccharomyces lysate, cetyl-20, stearth-20, stearic acid, salicylate, sodium hydroxide, tromethamine, methyl perfluorobutyl ether, isododecane, disodium succinate, silica, glutamic acid, glycine, threonine, valine.

Drug Facts (continued)

polyisobutene-11, oleic acid, dha 1, decyl glucoside, linoleol d-limonene, hexyl cinnamal, butylphenyl methylpropional, alpha-isomethyl ionone.

Drug Facts

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Avobenzone 3.00%	Sunscreen
Octinoxate 3.00%	Sunscreen
Octisalate 5.00%	Sunscreen
Octocrylene 6.00%	Sunscreen

Uses ■ Helps prevent sunburn.

Drug Facts (continued)

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Drug Facts (continued)

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.

Drug Facts (continued)

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

Directions

■ Apply liberally and every 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.

Inactive ingredients

water, glycerin, butylene glycol, aluminum starch octenylsuccinate, c12-15 alkyl benzoate, cyclohexaxaloxane, cetylaryl alcohol, dimethicone, isooctenyl acetate, glyceryl stearate, phenoxethanol, ethylhexylglycerin, hydroxymethyl hexyl lactone crosspolymer, cetyl alcohol, ceteareth-20.

Formulado en Francia
Formulated in France
Colombia
San Juan, Puerto Rico 00926. Made in
PUERTO RICO: Dist. by Ventura Corp. Ltd.

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

avobenzone, octinoxate, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-957
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-75 STEARATE (UNII: OT38R0N74H)	
ANNICKIA CHLORANTHA BARK (UNII: H70115MP4A)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SACCHAROMYCES LYSATE (UNII: R85W246Z1C)	
CETETH-20 (UNII: I835H2IHHX)	
STEARETH-20 (UNII: L0Q8IK9E08)	
SILANEDIOL SALICYLATE (UNII: C054DF30K0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
TROMETHAMINE (UNII: 023C2WHX2V)	
METHYL PERFLUOROBUTYL ETHER (UNII: H637A50B7U)	
ISODODECANE (UNII: A8289P68Y2)	
SODIUM SUCCINATE ANHYDROUS (UNII: V8ZGC8ISR3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLUTAMIC ACID (UNII: 3KX376GY7L)	
GLYCINE (UNII: TE7660XO1C)	

THREONINE (UNII: 2ZD004190S)
VALINE (UNII: HG18B9YRS7)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
OLEANOLIC ACID (UNII: 6SMK8R7TGJ)
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-957-02	1 in 1 BOX	07/08/2016	
1	NDC:13537-957-01	50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:13537-957-04	1 in 1 BOX	07/08/2016	
2	NDC:13537-957-03	5 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:13537-957-06	1 in 1 CARTON	07/08/2016	
3	NDC:13537-957-05	1 mL in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:13537-957-08	1 in 1 CARTON	07/08/2016	
4	NDC:13537-957-07	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	07/08/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-957)

Revised: 7/2016

Ventura Corporation LTD