

LBEL PROTEGE EXPERT- octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide 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
PROTÈGE
EXPERT
sunscreen for eyes
contour and lips
SPF 30**

Drug Facts

Active Ingredients

Octinoxate 7.5%, Octisalate 4%, Octocrylene 10%, Oxybenzone 6%, Titanium dioxide 1%

Purpose

sunscreen

Uses

- Helps prevent sunburn.
- Higher SPF gives more sunburn protection.
- Provides high protection against sunburn
- Retains SPF after 40 minutes of activity in the water.

Warnings

For external use only.

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash or irritation develops and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally before sun exposure and as needed

Other information

- Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreen may reduce the risk of skin aging, skin cancer, and other harmful effects of the sun.

Inactive ingredients

Ozokerite, hydrogenated vegetable oil, petrolatum, butyrospermum parkii (butyrospermum parkii (shea

butter)), ricinus communis seed oil (ricinus communis (castor) seed oil), c12-15 alkyl benzoate, isopropyl lanolate, paraffin, copernicia cerifera cera (copernicia cerifera (carnauba) wax), isopropyl myristate, bht, propylparaben, tocopheryl acetate, octyldodecanol, cera microcristallina (microcrystalline wax), bha, phospholipids, cholesterol, cera alba (beeswax), cetearyl alcohol, cetearyl glucoside, euphorbia cerifera (candelilla) wax, polyglyceryl-2 dipolyhydroxystearate, glycosphingolipids

US: Dist. by Ventura International Ltd, San Francisco, CA 94111.

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

PRINCIPAL DISPLAY PANEL - 5 g Bottle Carton

L'BEL

PROTÈGE
EXPERT

sunscreen for eyes
contour and lips
SPF 30

WATER RESISTANT

5 g e (.17 oz.)

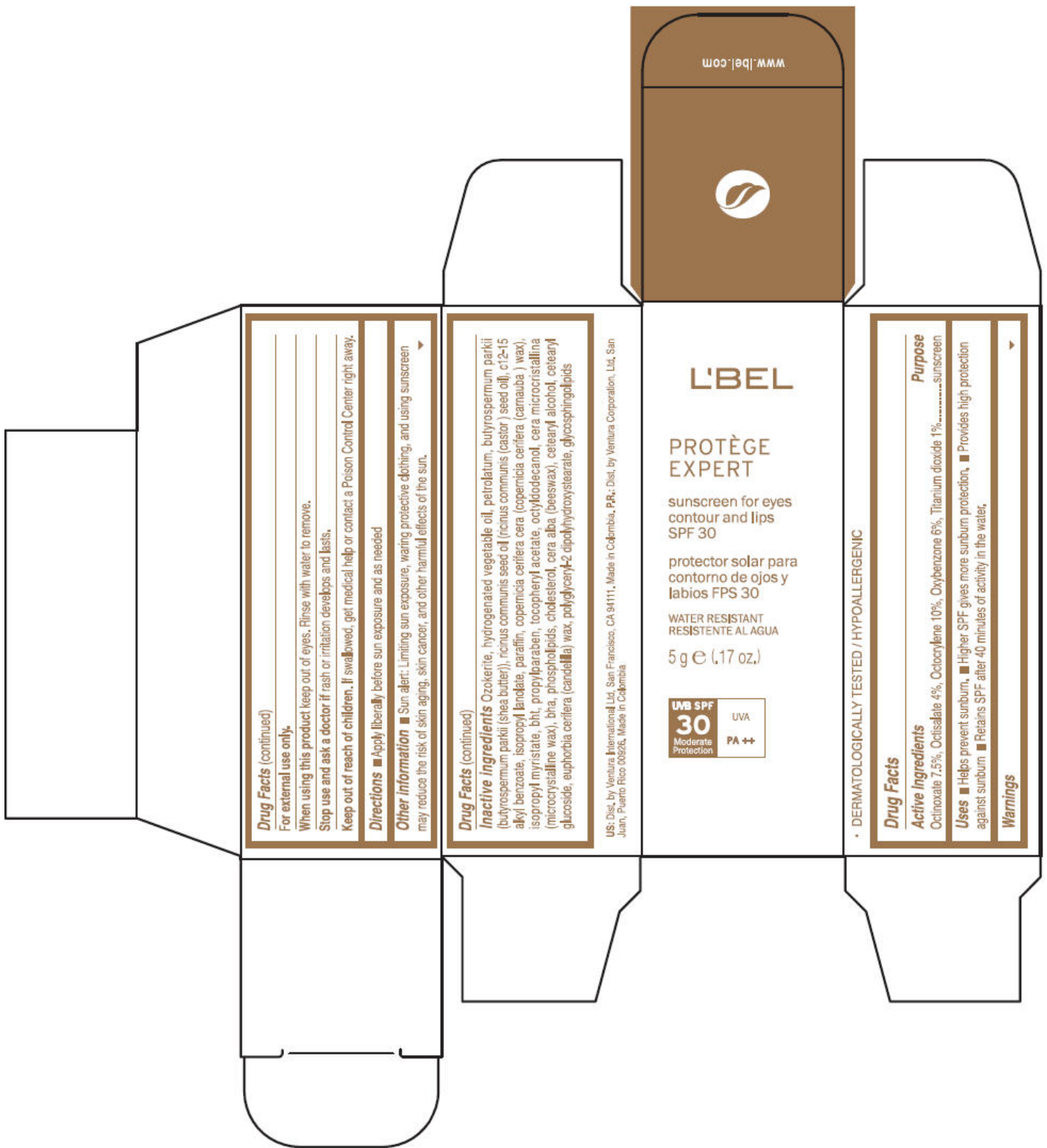
UVB SPF

30

Moderate
Protection

UVA

PA ++



LBEL PROTEGE EXPERT

octinoxate, octisalate, octocrylene, oxybenzone, and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-028
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.075 g in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	0.04 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.1 g in 1 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.06 g in 1 g
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
petrolatum (UNII: 4T6H12BN9U)	
shea butter (UNII: K49155WL9Y)	
castor oil (UNII: D5340Y2I9G)	
alkyl (c12-15) benzoate (UNII: A9EJ3J61HQ)	
paraffin (UNII: I9O0E3H2ZE)	
carnauba wax (UNII: R12CBM0EIZ)	
isopropyl myristate (UNII: 0RE8K4LNJS)	
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
propylparaben (UNII: Z8IX2SC1OH)	
octyldodecanol (UNII: 461N1O614Y)	
microcrystalline wax (UNII: XOF597Q3KY)	
butylated hydroxyanisole (UNII: REK4960K2U)	
cholesterol (UNII: 97C5T2UQ7J)	
yellow wax (UNII: 2ZA36H0S2V)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
cetearyl glucoside (UNII: 09FUA47KNA)	
candelilla wax (UNII: WL0328HX19)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13537-028-02	1 in 1 CARTON		
1	NDC:13537-028-01	5 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	08/10/2011	

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

Name	Address	ID/FEI	Business Operations
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