

**LBEL DEFENSE TOTAL COMPACT SUNSCREEN SPF 50 FOR FACE - MATTE FINISH-
octinoxate, octocrylene, and zinc oxide cream
Ventura International 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 Défense Total Compact Cream Sunscreen SPF 50 For Face - Matte Finish

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
OCTINOXATE 7%	Sunscreen
OCTOCRYLENE 5%	Sunscreen
ZINC OXIDE 16.66%	Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

- **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:
 - after 40 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- Children under 6 months of age: Ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m.–2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses.

Other information

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

Inactive ingredients

DIMETHICONE, ZEA MAYS (CORN) STARCH, POLYMETHYLSILSESQUIOXANE, POLYETHYLENE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, MICA, OZOKERITE, BUTYROSPERMUM PARKII (SHEA) BUTTER, SORBITAN SESQUIOLEATE, PEG/PPG-18/18 DIMETHICONE, PHENOXYETHANOL, TRIETHOXYCAPRYLYLSILANE, DIISOPROPYL ADIPATE, COPERNICIA CERIFERA (CARNAUBA) WAX, TOCOPHERYL ACETATE, CERAMIDE 3, CAPRYLYL GLYCOL, CHLORPHENESIN, PHYSALIS ANGULATA EXTRACT, FRAGRANCE, CAPRYLIC/CAPRIC TRIGLYCERIDE, SILICA, TRIMETHYLSILOXYSILICATE, OXOTHIAZOLIDINE, LINALOOL.

MAY CONTAIN: TITANIUM DIOXIDE, IRON OXIDES.

Dist. by Ventura Int
Ltd. DBA Belcorp USA, Miami,
FL 33126.

PRINCIPAL DISPLAY PANEL - 9,5 g Container Box

MEDIUM

L'BEL
DÉFENSE TOTAL

HIGH PROTECTION
SPF
50

compact cream sunscreen
for face - matte finish

BROAD SPECTRUM
WATER RESISTANT (40 minutes)

Net Wt. 0.34 oz. e (9,5 g)



L'BEL
DÉFENSE
TOTAL

MEDIUM

MEDIUM

L'BEL
DÉFENSE TOTAL

HIGH PROTECTION
SPF

50

protector solar para rostro
en **crema compacta** FPS 50 acabado mate
compact cream sunscreen
for face - matte finish

BROAD SPECTRUM
WATER RESISTANT (40 minutes)

Net Wt. 0.34 oz. e (9,5 g)

RECOMMENDED



DAILY USE

THE SKIN CANCER
FOUNDATION
RECOMMENDS THIS
PRODUCT AS AN
EFFECTIVE BROAD
SPECTRUM SUNSCREEN

U.S.A.: Dist. by Ventura Int
Ltd, DBA Belcoro USA, Miami,
FL 33126, PUERTO RICO:
Dist. by Ventura Corp. Ltd.,
San Juan, Puerto Rico 00926.

Made in Colombia.

www.lbel.com

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OCTINOXATE 7% Sunscreen
OCTOCRYLENE 5% .. Sunscreen
ZINC OXIDE 16.66% .. Sunscreen

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Drug Facts (continued)

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octinoxate, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	0.07 g in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.05 g in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.1666 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
MICA (UNII: V8A1AW0880)	
CERESIN (UNII: Q1LS2UJO3A)	
SHEA BUTTER (UNII: K49155WL9Y)	
SORBITAN SESQUOLEATE (UNII: 0W8RRI5W5A)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CERAMIDE NP (UNII: 4370DF050B)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
OXOTHIAZOLIDINE (UNII: M6U1ZG59XD)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-111-02	1 in 1 BOX	04/18/2017	
1	NDC:14783-111-01	9.5 g in 1 CONTAINER; 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	04/18/2017	

Labeler - Ventura International LTD (603192787)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-111)

Revised: 6/2017

Ventura International LTD