

**LBEL DEFENSE TOTAL BROAD SPECTRUM SPF 50 PLUS SUNSCREEN FOR FACE AND BODY- avobenzone, homosalate, and octocrylene lotion**  
**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 Defense Total broad spectrum SPF 50+ s sunscreen lotion for face and body**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Avobenzone 3.00%	Sunscreen
Homosalate 10.00%	Sunscreen
Octocrylene 8.00%	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**

WATER, BUTYLOCTYL SALICYLATE, DIMETHICONE, POTASSIUM CETYL PHOSPHATE, POLYMETHYLSILSESQUIOXANE, C12-15 ALKYL BENZOATE, CYCLOHEXASILOXANE, ETHYLHEXYL METHOXYCRYLENE, PHENETHYL BENZOATE, PROPYLENE GLYCOL, VP/EICOSENE COPOLYMER, SILICA, TRIMETHYLSILOXYSILICATE, PHENOXYETHANOL, CETYL PALMITATE, HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER, FRAGRANCE, PHYSALIS ANGULATA EXTRACT, CAPRYLIC/CAPRIC TRIGLYCERIDE, CETEARYL ALCOHOL, PENTAERYTHRITYL TETRA-DI-T-BUTYL HYDROXYHYDROCINNAMATE, XANTHAN GUM, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER, CAPRYLYL GLYCOL, DISODIUM EDTA, TOCOPHERYL ACETATE, BUTYLENE GLYCOL, CITRIC ACID, OXOTHIAZOLIDINE.

Dist. by Ventura Int Ltd. DBA Belcorp USA,  
San Francisco, CA 94111.

**PRINCIPAL DISPLAY PANEL - 10 ml Bottle Carton**

**L'BEL**  
DÉFENSE  
TOTAL

HIGH PROTECTION  
SPF  
**50+**

broad spectrum  
sunscreen  
**lotion** for face  
and body

WITH COLLAGEN  
BIO-PROTECTORS

**WATER RESISTANT**  
**(40 minutes)**

10 ml e (.33 fl.oz.)

www.lbel.com



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**WATER RESISTANT**  
(40 minutes)

10 ml e (.33 fl.oz.)

### Drug Facts (continued)

P H O S P H A T E,  
POLYMETHYLSILSESQUOXANE,  
C12-15 ALKYL BENZOATE,  
CYCLOHEXASILOXANE, ETHYLHEXYL  
METHOXYCRYLENE, PHENETHYL  
BENZOATE, PROPYLENE GLYCOL,  
VPEIOSENE COPOLYMER, SILICA, ▶

### Drug Facts (continued)

TRIMETHYLSILOXYLLIGATE,  
PHENOXYETHANOL, CETYL  
PALMITATE, HDI/TRIMETHYLOL  
HEXYLLACTONE CROSSPOLYMER,  
FRAGRANCE, PHYSALIS ANGULATA  
EXTRACT, CAPRYLIC/CAPRIC  
TRIGLYCERIDE, CETEARYL ALCOHOL, ▶

### Drug Facts (continued)

PENTAERYTHRITYL TETRA-DI-T-BUTYL  
HYDROXYHYDROCINNAMATE,  
XANTHAN GUM, ACRYLATES/C10-30  
ALKYL ACRYLATE CROSSPOLYMER,  
CAPRYLYL GLYCOL, DISODIUM EDTA,  
TOCOPHERYL ACETATE, BUTYLENE  
GLYCOL, CITRIC ACID, OXOTHIAZOLIDINE

### Drug Facts

**Active Ingredients** **Purpose**  
Avobenzone 3.00%..... Sunscreen  
Homosalate 10.00%..... Sunscreen  
Octocrylene 8.00%..... Sunscreen

**Uses** ■ Helps prevent sunburn. ▶

### Drug Facts (continued)

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 ▶

### Drug Facts (continued)

■ 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. ▶

### Drug Facts (continued)

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**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. ▶

### Drug Facts (continued)

■ 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

### Drug Facts (continued)

• wear long-sleeved shirts, pants,  
hats, and sunglasses.

### Other Information

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

### Inactive Ingredients

WATER, BUTYLOCTYL SALICYLATE,  
DIMETHICONE, POTASSIUM CETYL ▶

US: Dist. by Ventura Int'l Ltd. DBA Belcorp USA  
San Francisco, CA 94111. Made in Colombia.  
PUERTO RICO: Dist. by Ventura Corp. Ltd.  
San Juan, Puerto Rico 00926. Made in  
Colombia.  
Formulated in France  
Made in Colombia

# LBEL DEFENSE TOTAL BROAD SPECTRUM SPF 50 PLUS SUNSCREEN FOR FACE AND BODY

avobenzone, homosalate, and octocrylene lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-383
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 mL
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	0.1 g in 1 mL
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	0.08 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OXOTHIAZOLIDINE (UNII: M6U1ZG59XD)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-383-01	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:14783-383-03	1 in 1 BOX		
2	NDC:14783-383-02	10 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:14783-383-05	1 in 1 PACKAGE		
3	NDC:14783-383-04	1 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	05/22/2015	

**Labeler** - Ventura International LTD (603192787)**Establishment**

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-383)

Revised: 5/2015

Ventura International LTD