

**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 DÉFENSE TOTAL broad spectrum SPF 50+ 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 [or 80] 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, d-LIMONENE, LINALOOL, CITRONELLOL.

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

## **PRINCIPAL DISPLAY PANEL - 80 ml Bottle Label**

**L'BEL  
DÉFENSE  
TOTAL**

**HIGH PROTECTION  
SPF  
50+**

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

**WITH COLLAGEN  
BIO-PROTECTORS**

**WATER RESISTANT  
(40 minutes)**

**80 ml e (2.7 fl.oz.)**

**L'BEL**  
**DÉFENSE**  
**TOTAL**

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 SPF  
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WITH COLLAGEN  
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WATER RESISTANT  
 (40 minutes)

80 ml e (2.7 fl.oz.)

**Drug Facts**

Active Ingredients	Purpose
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**

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

**Formulated in France**

[www.lbel.com](http://www.lbel.com)

**Drug Facts (continued)**

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**

**Drug Facts (continued)**

- 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, d-limonene, linalool, citronellol.

# FACE AND BODY

avobenzone, homosalate, and octocrylene lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:14783-965
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: 059QF0KO0R)	
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: HIE492ZZ3T)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE 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)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
OXOTHIAZOLIDINE (UNII: M6U1ZG59XD)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14783-965-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/18/2016	
2	NDC:14783-965-02	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/18/2016	
3	NDC:14783-965-04	1 in 1 BOX	08/18/2016	
3	NDC:14783-965-03	10 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:14783-965-05	5 mL in 1 PACKET; Type 0: Not a Combination Product	08/18/2016	
5	NDC:14783-965-06	1 mL in 1 PACKET; Type 0: Not a Combination Product	08/18/2016	
6	NDC:14783-965-08	1 in 1 CARTON	08/18/2016	
6	NDC:14783-965-07	0.07 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	08/18/2016	

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

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(14783-965)

Revised: 12/2019

Ventura International LTD