

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

Drug Facts

<i>Active Ingredients</i>	<i>Purpose</i>
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.

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

PRINCIPAL DISPLAY PANEL - 10 ml Tube Box

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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(40 minutes)**

10 ml e (.33 fl.oz.)

Drug Facts (continued)

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

Drug Facts (continued)

TRIMETHYLSILOXY SILICATE,
PHENOXYETHANOL, CETYL
PALMITATE, HDI/TRIMETHYLOL
HEXYLLACTONE CROSSPOLYMER
FRAGRANCE, PHYSALIS ANGIULATA
EXTRACT, CAPRYLIC/CAPRIC
TRIGLYCERIDE, CETEARYL ALCOHOL. ▶

Drug Facts (continued)

PENTAEERYTHRITYL TETRA-DI-T-BUTYL
HYDROXYHYDROCIINNAMATE,
XANTHAN GUM, ACRYLATES/C10-30
ALKYL ACRYLATE CROSSPOLYMER,
CAPRYLYL GLYCOL, DISODIUM EDTA,
TOCOPHERYL ACETATE, BUTYLENE
GLYCOL, CITRIC ACID, OXOHAZOLINONE. ▶

Drug Facts

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

Uses ■ Helps prevent sunburn. ▶

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)

■ 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)

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)

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. ▶

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, BUTYL OCTYL SALICYLATE, DIMETHICONE, POTASSIUM CETYL ▶

US. Dist. by Ventura Int'l Ltd. DSA BeCorp. 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 50PLUS SUNSCREEN FOR FACE AND BODY

avobenzone, homosalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-383
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: 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)	
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:13537-383-01	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:13537-383-03	1 in 1 BOX		
2	NDC:13537-383-02	10 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:13537-383-05	1 in 1 PACKAGE		
3	NDC:13537-383-04	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 Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	MANUFACTURE(13537-383)

Revised: 5/2015

Ventura Corporation LTD