

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 [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.
- 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 Corp, Ltd., San Juan, Puerto Rico 00926

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.)

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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

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.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13537-990
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:13537-990-01	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2016	
2	NDC:13537-990-02	80 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/23/2016	
3	NDC:13537-990-04	1 in 1 BOX	08/23/2016	
3	NDC:13537-990-03	10 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:13537-990-05	5 mL in 1 PACKET; Type 0: Not a Combination Product	08/23/2016	
5	NDC:13537-990-06	1 mL in 1 PACKET; Type 0: Not a Combination Product	08/23/2016	
6	NDC:13537-990-08	1 in 1 CARTON	08/23/2016	
6	NDC:13537-990-07	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	08/23/2016	

Labeler - Ventura Corporation LTD (602751344)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(13537-990)

Revised: 11/2020

Ventura Corporation LTD