DEFENSE TOTAL HIGH PROTECTION SPF 50 NO COLOR DAILY NON-GREASY FACE PROTECTION- homosalate, octocrylene, avobenzone 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.

Defense Total SPF 50 No Color Daily Non-Greasy Face Protection

Active Ingredients Purpose

Homosalate 10.00% Sunscreen

Octocrylene 8.00% Sunscreen

Avobenzone 3.00% 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.

Keep out of reach of children. If swallowed, get medical help or contact a poison Control Center right away

Stop use and ask a doctor if rash occurs

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.

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: \bullet limit your time in the sun, especially from $10\,$

a.m. -2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses

• Children under 6 months of age: ask a doctor.

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.

Other information:

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

Inactive Ingredients

Water, styrene/acrylates copolymer, potassium cetyl phosphate, c12·15 alkyl benzoate, cyclohexasiloxane, dimethicone,

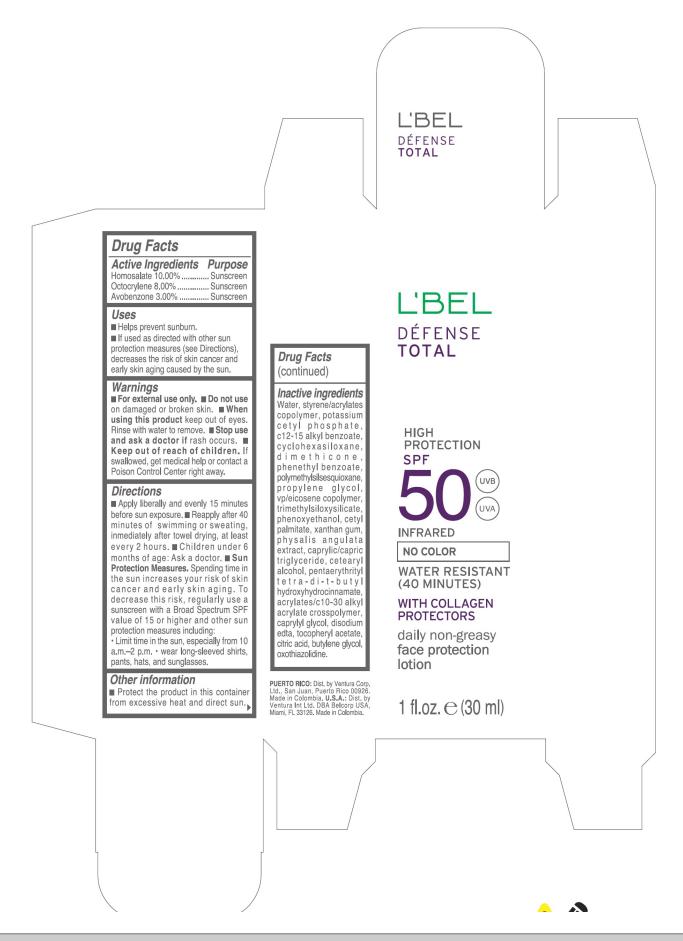
phenethyl benzoate,polymethylsilsesquioxane, propylene glycol, vp/eicosene copolymer, trimethylsiloxysilicate, phenoxyethanol,

cetyl palmitate, xanthan gum, physalis angulata extract, caprylic/capric triglyceride, cetearyl alcohol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, acrylates/c10·30 alkyl acrylate crosspolymer, caprylyl glycol, disodium edta, tocopheryl acetate, citric acid, butylene glycol, oxothiazolidine.

Defense Total High Protection SPF 50

No color

Water resistant (40 minutes) with collagen protectors daily non-greasy
Face protection Lotion
1 fl. oz. (30 ml)



DEFENSE TOTAL HIGH PROTECTION SPF 50 NO COLOR DAILY NON-GREASY FACE PROTECTION

homosalate, octocrylene, avobenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43596-0140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	8 g in 100 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 g in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
OXOTHIAZOLIDINE (UNII: M6U1ZG59XD)		
PHENO XYETHANOL (UNII: HIE492ZZ3T)		
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)		
XANTHAN GUM (UNII: TTV12P4NEE)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)		
PHYSALIS ANGULATA WHO LE (UNII: W4TKW9 D5GG)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)		
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)		
CAPRYLYL GLYCOL (UNII: 00 YIU5438 U)		
PHENETHYL BENZOATE (UNII: 0 C1439 29 GK)		
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)		
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)		
WATER (UNII: 059QF0KO0R)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
DIMETHICO NE (UNII: 92RU3N3Y1O)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)		
CETYL PALMITATE (UNII: 5ZA2S6B08X)		
CYCLOMETHICONE 6 (UNII: XHK3U310BA)		

Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:43596-0140-1	30 mL in 1 BOX; Type 0: Not a Combination Product	06/29/2020	

ı	Marketing Infor	mation		
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	06/29/2020	

Labeler - Ventura Corporation LTD (602751344)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bel Star S.A. (Colombia)		880160197	manufacture(43596-0140)	

Revised: 12/2020 Ventura Corporation LTD