

**DEFENSE TOTAL HIGH PROTECTION SPF 50 NO COLOR DAILY NON-GREASY
FACE PROTECTION- homosalate, octocrylene, avobenzone lotion
Bel Star S.A. (Colombia)**

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 High Protection SPF 50 No Color Daily Non-Greasy Face Protection

Drug Facts

Active ingredients

Homosalate 10.00%

Octocrylene 8.00%

Avobenzone 3.00%

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 product is 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, 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, xanthan gum, cetearyl alcohol, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, acrylates/c10-30 alkyl acrylate crosspolymer, caprylyl glycol, disodium edta, tocopheryl acetate, citric acid

Company Information

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

Made in Colombia.

U.S.A.: Dist. by Ventura Int Ltd. DBA Belcorp USA, Miami, FL 33126.

Purpose

Sunscreen

Product Packaging



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:14141-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	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
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHYSALIS ANGULATA WHOLE (UNII: W4TKW9D5GG)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14141-140-01	30 mL in 1 BOX; Type 0: Not a Combination Product	06/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	06/29/2020	

Labeler - Bel Star S.A. (Colombia) (880160197)

Establishment

Name	Address	ID/FEI	Business Operations
Bel Star S.A. (Colombia)		880160197	manufacture(14141-140)

