PANAMA JACK BROAD SPECTRUM SPF 15- avobenzone, octisalate, octocrylene lotion Prime Enterprises Inc.

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.

Panama Jack 15 Broad Spectrum SPF 15 Sunscreen Lotion

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 2%

Purpose

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 product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 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 broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses

• children under 6 months: Ask a doctor

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Isopropylphthalimide, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propylene Glycol, Sodium Hydroxide, Stearyl Alcohol, Tocopheryl Acetate, Ubiquinone, Water, Xanthan Gum

Other information

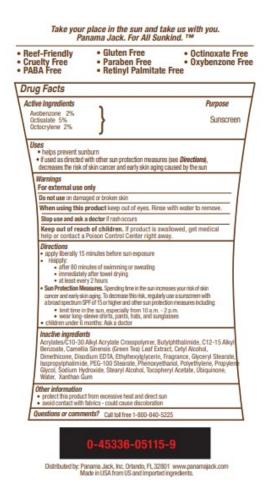
- protect this product from excessive heat and direct sun
- avoid contact with fabrics could cause discoloration

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack 15 Broad Spectrum SPF 15 Sunscreen Lotion





PANAMA JACK BROAD SPECTRUM SPF 15

avobenzone, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0283
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.74 mg in 1 mL	
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	49.35 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	19.74 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
WATER (UNII: 059QF0KO0R)			
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)			
STEARYL ALCOHOL (UNII: 2KR8914H1Y)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
UBIDECARENO NE (UNII: EJ27X76M46)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
XANTHAN GUM (UNII: TTV12P4NEE)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
PEG-100 STEARATE (UNII: YD01N1999R)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)			

Product Characteristics				
Color	white	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

I	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0283-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 2/15/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 2/15/20 19	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address		Business Operations
Prime Enterprises Inc.		10 19 46 0 28	pack(58443-0283), manufacture(58443-0283), label(58443-0283), analysis(58443-0283)

Revised: 1/2021 Prime Enterprises Inc.