PANAMA JACK SPF 4- 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 4 SPF 4 Sunscreen Lotion

Active Ingredients

Octocrylene 2%

Purpose

Sunscreen

Uses

• helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Specnding time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

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
- children under 6 months: Ask a doctor

Inactive ingredients

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

Other information

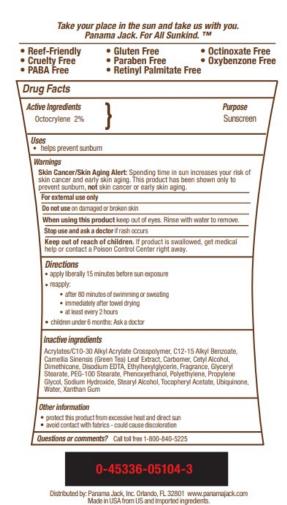
- protect this product from excessive heat and direct sun
- avoid contact with fabrics could cause discoloration

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack 4 SPF 4 Sunscreen Lotion





PANAMA JACK SPF 4

octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0289
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	19.12 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
CETYL ALCOHOL (UNII: 936JST6JCN)			
WATER (UNII: 059QF0KO0R)			
SODIUM HYDROXIDE (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: 7FLD9 1C8 6 K)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
PEG-100 STEARATE (UNII: YD01N1999R)			
CARBOMER 980 (UNII: 4Q93RCW27E)			

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Pá	nckaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1	NDC:58443-0289-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	0 2/0 1/20 19	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 2/0 1/20 19	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0289), manufacture(58443-0289), label(58443-0289), analysis(58443-0289)

Revised: 1/2021 Prime Enterprises Inc.