

PANAMA JACK 30 BROAD SPECTRUM SPF 30 CLEAR ZINC- octinoxate, octisalate, octocrylene, and zinc oxide 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.

Active ingredients Octinoxate 5%, Octisalate 5%, Octocrylene 2%, Zinc Oxide 3%

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 a 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

Aluminium Starch Octenylsuccinate, Bis-PEG-12 Dimethicone Beeswax, Cetyl PEG/PPG-10/1 Dimethicone, Decyl Glucoside, Diazolidinyl Urea, Diisodecyl Adipate, Disodium EDTA, Glycerin, Hexyl Laurate, Hydrogenated Castor Oil, Methylparaben, Mineral Oil, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Propylparaben, Silica, Sodium Chloride, Tocopheryl Acetate, Triethoxycaprylsilane, Water

Other information Protect this product from excessive heat and direct sun

Distributed by: Panama Jack, Inc. Orlando, FL. 32801 1-800-840-5225

PRINCIPAL DISPLAY PANEL - 30mL Bottle Label



Panama Jack
 SUNSCREEN
 LOTION
 1 FL OZ (30mL)
 30 BROAD SPECTRUM SPF 30
 CLEAR ZINC
 WATER RESISTANT (80 MINUTES)

PANAMA JACK 30 BROAD SPECTRUM SPF 30 CLEAR ZINC

octinoxate, octisalate, octocrylene, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0179
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	49.35 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.35 in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	19.74 in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	29.61 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
BIS-PEG-10 DIMETHICONE/DIMER DILINOLEATE COPOLYMER (UNII: CF5W1YCX11)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
DIISODECYL ADIPATE (UNII: 3V0Q382O0P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)	
MINERAL OIL (UNII: T5L8T28FGP)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0179-3	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/29/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/29/2011	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0179) , pack(58443-0179) , manufacture(58443-0179) , analysis(58443-0179)

Revised: 1/2020

Prime Enterprises, Inc.