

PANAMA JACK SPF 4- octinoxate oil
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 2 %

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/SkinAging Alert: Spending time in the sun increases ou 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, Cetyl Alcohol, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glyceryl Stearate, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propylene Glycol, Stearyl Alcohol, Tocopheryl Acetate, Triethanolamine, Ubiquinone, Water (Aqua), Xanthan Gum

Other information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-800-840-5225 www.panamajack.com

Email us at info@panamajack.com

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

Sunscreen Lotion SPF 4

Drug Facts	Purpose
Active Ingredients: Octinoxate 2%	Sunscreen
Uses • helps prevent sunburn	
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0 45336 05104 3
Formulated with Love, Care and Pride since 1974
Distributed by: Panama Jack, Inc. Orlando, FL 32801 Made in USA

Panama Jack

SPF 4

Dark Tanning Lotion

WATER RESISTANT (80 MINUTES)

Non Greasy & Hypoallergenic with

CoQ10 Antioxidant, Green Tea & Vitamin E

6 FL OZ (177mL)

PANAMA JACK SPF 4

octinoxate oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	19.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
UBIDECARENONE (UNII: EJ27X76M46)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:58443-0065-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/12/2013	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		01/12/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0065) , pack(58443-0065) , manufacture(58443-0065) , analysis(58443-0065)

Revised: 1/2020

Prime Enterprises, Inc.