

**PANAMA JACK SPF 8- octinoxate, and oxybenzone 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.*

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**Active ingredients**

Octinoxate 2 %, and Oxybenzone 2 %

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending 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, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Caramel, Carrageenan, Citric Acid, Dimethicone, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Oleth 10, Propylene Glycol, Propylparaben, Soluble Collagen, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Trimethylsiloxysilicate, Water

**Other information**

- protect this product from excessive heat and direct sun

Questions or Comments?

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

**PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label**



Panama Jack

SPF 8

SUNSCREEN

Lotion

WATER RESISTANT (80 MINUTES)

Non Greasy and Hypoallergenic with  
CoQ10 Anioxidan, Green Tea & Vitamin E

6 FL OZ (177 mL)

# PANAMA JACK SPF 8

octinoxate, and oxybenzone lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0051
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	19.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.5 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
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)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.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:58443-0051-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/25/2013	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/25/2013	

**Labeler** - Prime Enterprises, Inc. (101946028)

**Registrant** - Prime Enterprises, Inc. (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0051) , pack(58443-0051) , manufacture(58443-0051) , analysis(58443-0051)

Revised: 1/2020

Prime Enterprises, Inc.