

PANAMA JACK SPF 15- octinoxate, octisalate and oxybenzone spray
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 3 % 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, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glyceryl Stearate, Isopropylphthalimide, 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

Panama Jack
SPF 15
SUNSCREEN Lotion
WATER RESISTANT (80 MINUTES)
Non Greasy & Hypoallergenic with CoQ10 Antioxidant, Green Tea & Vitamin E
6 FL OZ (177 mL)

Sunscreen Lotion SPF 15

Drug Facts	Purpose
Active Ingredients Octinoxate 5% Octisalate 3% Oxybenzone 2%	Sunscreen
Uses • helps prevent sunburn	
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0 45336 05115 9
Formulated with Love, Care and Pride since 1974
Distributed by: Panama Jack, Inc. Orlando, FL 32801 Made in USA

Panama Jack

SPF 15

SUNSCREEN

Lotion

WATER RESISTANT (80 MINUTES)

Non Greasy & Hypoallergenic with

CoQ10 Antioxidant, Green Tea & Vitamin E

6 FL OZ (177 mL)

PANAMA JACK SPF 15

octinoxate, octisalate and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	48.4 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	29 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0 Y) (OXYBENZONE - UNII:950OS7VE0 Y)	OXYBENZONE	19.3 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)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
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:58443-0052-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/25/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0052) , pack(58443-0052) , manufacture(58443-0052) , analysis(58443-0052)

Revised: 1/2020

Prime Enterprises, Inc.