

PANAMA JACK BROAD SPECTRUM SPF 70- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray
Prime Packaging, 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

Avobenzone 3 %, Homosalate 12.5 %, Octisalate 5 %, Octocrylene 2.75 %, Oxybenzone 6 %

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.

Flammable: Do not use near heat, flame or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120 °F

Directions

- spray liberally and spread by hand 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 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
- Hold container 4 to 6 inches from the skin to apply
- **Do not spray directly into face.** Spray on hands then apply to face.
- Do not apply in windy conditions. Use in well ventilated areas.

Inactive Ingredients

Diethylhexyl 2,6-Naphthalate, Fragrance, Polyester-8, SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other information

- protect this product from excessive heat and direct sun. May stain some fabrics

Questions or Comments?

Call toll free 1-800-840-5225

PRINCIPAL DISPLAY PANEL - 177 mL Can Label

CONTINUOUS CLEAR SUNSCREEN SPRAY SPF 70

Drug Facts	
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Flammable Do not use near heat, flame or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120° F.

Directions:

- Spray liberally and evenly by hand 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:
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CONTINUOUS CLEAR SUNSCREEN SPRAY SPF 70

Distributed by: Panama Jack, Inc.
Orlando, FL 32801 Made in USA

www.panamajack.com
Panama Jack.
Formulated with Love, Care and Pride since 1974

Panama Jack

SPF

70

BROAD SPECTRUM SPF 70

CONTINUOUS CLEAR

SUNSCREEN SPRAY

WATER RESISTANT (80 MINUTES)

NON-GREASY FORMULA

QUICK & EVEN COVERAGE

6 FL OZ (177 mL)

PANAMA JACK BROAD SPECTRUM SPF 70

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0036
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	106.8 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	42.7 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	23.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	51.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13630-0036-4	177 mL in 1 CAN; Type 0: Not a Combination Product	02/21/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	02/21/2012		

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0036) , analysis(13630-0036)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0036) , pack(13630-0036)

Revised: 1/2020

Prime Packaging, Inc.