

**PAMANA JACK SPORT BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene 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.*

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**Panama Jack Sport Broad Spectrum SPF 50 Sunscreen Spray**

***Active Ingredients***

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

***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. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F.

**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.

***Directions***

- Spray liberally and spray evenly by hand 15 minutes before sun exposure
- 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
- 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-sleeved shirts, pants, hats, and sunglasses
- Children under 6 months: Ask a doctor

***Inactive ingredients***

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

***Other information***

- Protect this product from excessive heat and direct sun.
- Avoid spraying on fabrics-could cause discoloration.

***Questions or comments?***

Call toll free 1-800-840-5225

**Panama Jack Sport Broad Spectrum SPF 50**

**Panama Jack.**



**Broad Spectrum  
SPF 50  
Sunscreen Spray**

**50**

UVA / UVB Protection  
Paraben Free • PABA Free  
Water Resistant  
(80 Minutes)



**NET WT. 5.5 OZ (155g)**

*Made with Love, Care and Pride since 1974, Panama Jack's trusted sun protection helps everyone enjoy A Kinder Sun.*

• Reef-Friendly • Gluten Free • Octinoxate Free  
• Cruelty Free • Paraben Free • Oxybenzone Free  
• PABA Free • Retinyl Palmitate Free

#### Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 5%	Sunscreen

**Uses**  
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• 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.

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Call toll free 1-800-840-5225



Distributed by: Panama Jack, Inc.  
Orlando, FL 32801 www.panamajack.com  
Made in USA from US and Imported ingredients.



## PAMANA JACK SPORT BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0141
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.55 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	88.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	44.25 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	44.25 mg in 1 mL	
Inactive Ingredients				
Ingredient Name			Strength	
VINYL ACETATE (UNII: L9MK238N77)				
DIBUTYL MALEATE (UNII: 4X371TMK9K)				
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)				
ALCOHOL (UNII: 3K9958V90M)				
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)				
Product Characteristics				
Color	yellow (Light Yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0141-4	150 mL in 1 CAN; Type 0: Not a Combination Product	01/29/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		01/29/2019	

**Labeler** - Prime Packaging, Inc. (805987059)

**Registrant** - Prime Packaging, Inc. (805987059)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0141) , analysis(13630-0141)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0141) , pack(13630-0141)