

**PAMANA JACK BROAD SPECTRUM SPF 100- 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 100 Broad Spectrum SPF 100 Sunscreen Spray**

***Active Ingredients***

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

***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, SD Alcohol 40-B, Trimethoxybenzylidene Pentanedione, 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 100 Broad Spectrum SPF 100 Sunscreen Spray**

Take your place in the sun and take us with you.  
Panama Jack. For All Sunkind.™

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

**Drug Facts**

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**Questions or comments?**  
 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.

0 45336 04199 0

**100**  
**BROAD SPECTRUM**  
**SPF 100**

**REEF FRIENDLY**

**Sunscreen Spray**  
 Cruelty Free • Gluten Free  
 Water Resistant (80 Minutes)

NET WT. 5.5 OZ (155 g)

## PAMANA JACK BROAD SPECTRUM SPF 100

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0147
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.01 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	130.05 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	43.35 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	86.7 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
VINYL ACETATE (UNII: L9MK238N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
ALCOHOL (UNII: 3K9958V90M)	
TRIMETHOXYBENZYLIDENE PENTANEDIONE (UNII: 322V0ACF25)	

## Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0147-4	178 mL in 1 CAN; Type 0: Not a Combination Product	03/14/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/14/2019	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0147) , analysis(13630-0147)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	pack(13630-0147) , label(13630-0147)