

**PANAMA JACK BROAD SPECTRUM SPF30- avobenzone, homosalate, octisalate, octocrylene, 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.*

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**Active ingredients**

Avobenzone 2 %, Homosalate 7.5 %, Octisalate 5 %, Octocrylene 2.75 %, and Oxybenzone 2 %

**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 evenly 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 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-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 (Parfum), 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 Bottle Label



**CONTINUOUS CLEAR SUNSCREEN SPRAY SPF 30+**

**Drug Facts**

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**NO CFCA**

**CONTINUOUS CLEAR SUNSCREEN SPRAY SPF 30+**

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

[www.panamajack.com](http://www.panamajack.com)  
Panama Jack.  
Formulated with Love, Care and Pride since 1974

0 45336 04130 3

**BROAD SPECTRUM SPF 30+**  
**CONTINUOUS CLEAR SUNSCREEN SPRAY**  
**WATER RESISTANT (80 MINUTES)**

**NON - GREASY FORMULA**  
**QUICK & EVEN COVERAGE**

6 FL OZ (177 mL)

Panama Jack

SPF 30

BROAD SPECTRUM SPF 30+

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SUNSCREEN SPRAY

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## PANAMA JACK BROAD SPECTRUM SPF30

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### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0056
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	62.625 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	41.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	22.9 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	16.7 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

### 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:58443-0056-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/21/2013
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## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/21/2013	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0056) , pack(58443-0056) , manufacture(58443-0056) , analysis(58443-0056)

Revised: 1/2020

Prime Enterprises, Inc.