

PANAMA JACK BROAD SPECTRUM SPF 100 SUNSCREEN- 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.

Panama Jack 100 Broad Spectrum SPF 100 Sunscreen Continuous Spray

Active Ingredients

Avobenzone 3%

Homosalate 15%

Octisalate 5%

Octocrylene 10%

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.

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 spread 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 and 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.

Inactive Ingredients

Caprylic/Capric Triglyceride, Diethylhexyl Syringylidene-malonate, Fragrance, 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.

Question or comments?

Call toll free 1-800-840-5225

Panama Jack 100 Broad Spectrum SPF 100 Sunscreen



PANAMA JACK BROAD SPECTRUM SPF 100 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0124
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.28 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	131.4 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	43.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	87.6 mg in 1 mL

OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	52.56 mg in 1 mL
--	------------	------------------

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL ACETATE (UNII: L9MK238N77)	
MONOBUTYL MALEATE (UNII: F2LD7FVO1L)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0124-4	177 mL in 1 CAN; Type 0: Not a Combination Product	01/24/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/24/2018	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0124) , analysis(13630-0124)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	label(13630-0124) , pack(13630-0124)