

**PANAMA JACK SUNSCREEN BROAD SPECTRUM SPF75- 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.

Panama Jack Broad Spectrum SPF 75 Sunscreen Spray

Active Ingredients

Avobenzone 3%

Homosalate 15%

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 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 a well-ventilated area
- 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

Inactive ingredients

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

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 Broad Spectrum SPF 75 Sunscreen Spray

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

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

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%	} Sunscreen
Octisalate 5%	
Homosalate 15%	
Octocrylene 10%	

Uses

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Questions or comments?
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NO CFCs
FORMULA TO PROTECT THE ENVIRONMENT

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

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PANAMA JACK SUNSCREEN BROAD SPECTRUM SPF75

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.89 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	43.15 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	86.3 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	129.45 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL ACETATE (UNII: L9MK238N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

Color	yellow (Colorless to light yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0259-4	180 mL in 1 CAN; Type 0: Not a Combination Product	03/21/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	03/21/2022	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0259) , analysis(13630-0259)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0259) , pack(13630-0259)

Revised: 11/2022

Prime Packaging, Inc.