

**PANAMA JACK SPF 8- avobenzone, 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 SPF 8 Bronzer Lotion C/S**

**Active ingredients**

Avobenzone 2 %, Octocrylene 2 %

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

**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.

Skin Cancer/Skin Aging Alert: Spending time in the sun increases you risk of skin cancer and early skin aging. this product has been shown only to prevent sunburn, not skin cancer or early aging.

**Directions**

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- 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 area

## Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadosis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Isopropylphthalimide, Oleth-10, Phenoxyethanol, Propylene Glycol, Retinyl Palmitate, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trimethylsiloxysilicate, Ubiquinone, Water

## 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

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

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

### Drug Facts

Active Ingredients:	PURPOSE
Avobenzone 2% Octocrylene 2%	Sunscreen

**Uses:**  
• helps prevent sunburn

**Warnings:**  
**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

**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.

**Directions:**  
• Spray liberally and evenly by hand 15 minutes before sun exposure  
• reapply:  
• after 80 minutes of swimming or sweating  
• immediately after towel drying  
• at least every 2 hours  
• 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:**  
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadosis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Isopropylphthalimide, Oleth-10, Phenoxyethanol, Propylene Glycol, Retinyl Palmitate, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trimethylsiloxysilicate, Ubiquinone, Water

**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

**0-45336-04608-7**

**Sunscreen Spray  
INSTANT BRONZER**  
Antioxidant • Moisturizing  
Water Resistant (80 Minutes)

NET WT. 5.5 OZ (155 g)

Distributed by: Panama Jack, Inc. Orlando, FL 32801 [www.panamajack.com](http://www.panamajack.com)  
Made in USA from US and imported ingredients.

# PANAMA JACK SPF 8

avobenzone, octocrylene spray

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0174
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0K00R)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CARAMEL (UNII: T9D99G2B1R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
UBIDECARENONE (UNII: EJ27X76M46)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLETH-10 (UNII: JD797EF70J)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	

## Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0174-4	155 g in 1 CAN; Type 0: Not a Combination Product	05/07/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/07/2019	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0174) , analysis(13630-0174)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	pack(13630-0174) , label(13630-0174)

Revised: 10/2020

Prime Packaging, Inc.