

PANAMA JACK BOAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

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.

Active ingredients

Avobenzone 3 %, Homosalate 10 %, 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.

Directions

- apply liberally 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

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glyceryl Stearate, Isopropylphthalimide, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol,

Polyethylene, Propylene Glycol, Stearyl Alcohol, Tocopheryl Acetate, Triethanolamine, Ubiquinone, Undecylcrylene Dimethicone, Water (Aqua), Xanthan Gum

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 www.panamajack.com

Email us at info@panamajack.com

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label

The image displays the principal display panel for a 177 mL bottle of Panama Jack Sunscreen Lotion SPF 50. The front of the bottle (left side) features a tropical background with palm leaves and a blue sky. At the top, there is a circular portrait of a man in a hat and sunglasses, with the brand name "Panama Jack" written in a stylized script below it. A large circular graphic contains "SPF 50". The text "SUNSCREEN Lotion" is prominently displayed, followed by "BROAD SPECTRUM SPF 50" and "WATER RESISTANT (80 MINUTES)". A yellow banner at the bottom of the front panel reads "Non Greasy & Hypoallergenic with CoQ10 Antioxidant, Green Tea & Vitamin E". The volume "6 FL OZ (177 mL)" is printed at the very bottom.

The back panel (right side) is titled "Sunscreen Lotion SPF 50" and contains the following information:

Drug Facts	Purpose
Active Ingredients Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen
Uses <ul style="list-style-type: none">• helps prevent sunburn• if used as directed with other sun protection measures (see <i>Directions</i>), 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.	
Directions <ul style="list-style-type: none">• apply liberally 15 minutes before sun exposure• reapply:<ul style="list-style-type: none">• 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: <ul style="list-style-type: none">• 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 Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Dimethicone, Disodium EDTA, Fragrance (Parfum), Glyceril Stearate, Isopropylthalamide, Methylisothiazolinone, PEG-100 Stearate, Phenoxyethanol, Polyethylene, Propylene Glycol, Stearyl Alcohol, Tocopheryl Acetate, Triethanolamine, Ubiquinone, Undecylcrylene Dimethicone, Water (Aqua), Xanthan Gum	
Other information <ul style="list-style-type: none">• protect this product from excessive heat and direct sun• may stain some fabrics	
Questions or comments? Call toll free 1-800-840-5225 www.panamajack.com Email us at info@panamajack.com	

At the bottom of the back panel, there is a barcode with the number "0 45336 05150 0" and the text "Formulated with Love, Care and Pride since 1974" and "Distributed by: Panama Jack, Inc. Orlando, FL 32801 Made in USA".

Panama Jack
SPF 50
SUNSCREEN
Lotion

BROAD SPECTRUM SPF 50

WATER RESISTANT (80 MINUTES)

Non Greasy & Hypoallergenic with

CoQ10 Antioxidant, Green Tea & Vitamin E

6 FL OZ (177 mL)

PANAMA JACK BOAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0054
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.2 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
UBIDECARENONE (UNII: EJ27X76M46)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0054-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/18/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0054) , pack(58443-0054) , manufacture(58443-0054) , analysis(58443-0054)

Revised: 1/2020

Prime Enterprises, Inc.