

PANAMA JACK BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene 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.

Panama Jack Baby Broad Spectrum SPF 50 Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 10%

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.

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 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, Cetyl Alcohol, Cetyl Phosphate, Disodium EDTA, Ethylhexylglycerin, Fragrance, Glyceryl Stearate, Glycyrrhiza Glabra (Licorice) Root Extract, PEG-100 Stearate, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Propylene Glycol, Silica, Sodium Hydroxide, Stearyl Alcohol, Tocopheryl Acetate, Ubiquinone, Water

Other information

- may stain some fabrics
- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack Baby Broad Spectrum SPF 50 Sunscreen Lotion

REEF FRIENDLY

Baby
Broad Spectrum
SPF 50

50

Sunscreen Lotion
Gentle Touch • Hypoallergenic
Paraben Free • PABA Free
Water Resistant (80 Minutes)
3 FL OZ (89 mL)

REEF FRIENDLY

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

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

Drug Facts

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REEF FRIENDLY

0 45336 08450 8

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

PANAMA JACK BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0285
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.73 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.55 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.55 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL PHOSPHATE (UNII: VT07D6X67O)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
UBIDECARENONE (UNII: EJ27X76M46)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0285-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	03/28/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/28/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0285) , manufacture(58443-0285) , label(58443-0285) , analysis(58443-0285)

Revised: 1/2021

Prime Enterprises Inc.