PANAMA JACK BROAD SPECTRUM SPF 15 SPORT- avobenzone, octisalate, and 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 Broad Spectrum SPF 15 Sport

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 1.85%

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.

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, Cetyl Alcohol, Disodium EDTA, Fragrance (Parfum), Glycyrrhiza Glabra (Licorice) Root Extract,

Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Phenyl Trimethicone, Polyethylene, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Propylparaben, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Ubiquinone, Undecylcrylene Dimethicone, Water (Aqua)

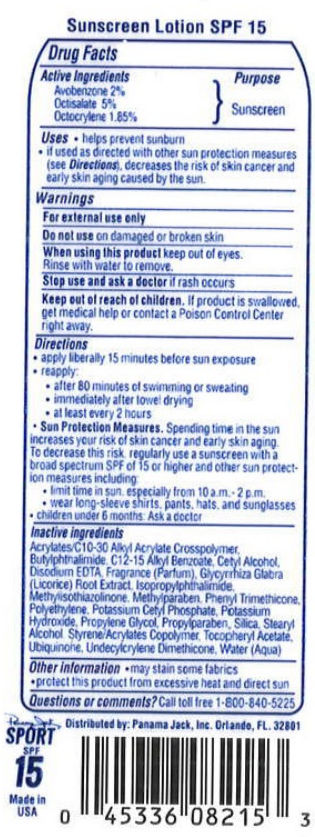
Other Information

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

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack Broad Spectrum SPF 15 Sunscreen



PANAMA JACK BROAD SPECTRUM SPF 15 SPORT

avobenzone, octisalate, and octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0159
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.6 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	18.13 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
LICORICE (UNII: 61ZBX54883)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
UBIQUINONE Q2 (UNII: I7T5V2W47R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0159-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2000	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/11/2000	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0159) , manufacture(58443-0159) , label(58443-0159) , analysis(58443-0159)

Revised: 1/2020 Prime Enterprises Inc.