PANAMA JACK SPF 85 SPORT DRY TOUCH SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray
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 Sport SPF 85 Dry Touch Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 12.5%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, Cetyl Alcohol, Disodium EDTA,

Fragrance, 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

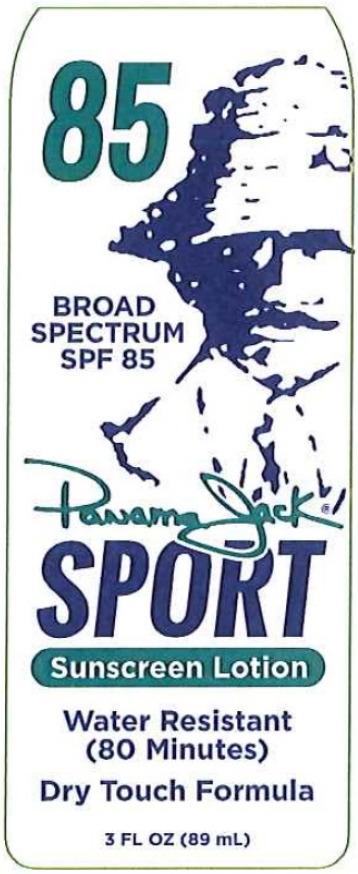
Other Information

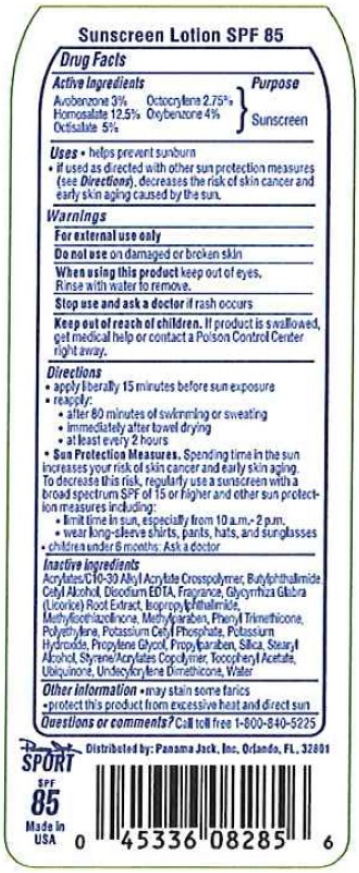
- may stain some fabrics
- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-800-840-5225

Panama Jack Sport SPF 85 Dry Touch Sunscreen





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avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0221
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	38.8 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.1 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	121.25 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26.68 mg in 1 mL

Inactive Ingredients

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

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0221-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/30/2011	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0221) , manufacture(58443-0221) , label(58443-0221) , analysis(58443-0221)

Revised: 1/2020 Prime Enterprises Inc.