

**PANAMA JACK BROAD SPECTRUM SPF 100 SPORT SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene, 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.*

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**100 Broad Spectrum SPF 100 Panama Jack Sport Sunscreen Lotion**

***Active Ingredients***

Avobenzone 3% Octocrylene 2.75%

Homosalate 15% Oxybenzone 4%

Octisalate 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, Butylphthalimide, Cetyl Alcohol, Disodium EDTA, Ethylhexylglycerin, Fragrance, Isopropylphthalimide, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, 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

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Sunscreen Lotion SPF 100		
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## PANAMA JACK BROAD SPECTRUM SPF 100 SPORT SUNSCREEN

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### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0257
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	38.04 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.58 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.55 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26.15 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	142.65 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0K00R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
UBIDECARENONE (UNII: EJ27X76M46)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
UNDECYLCRYLENE DIMETHICONE (10000 MW) (UNII: HA26P2LA4P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0257-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/21/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/21/2018	

**Labeler** - Prime Enterprises Inc. (101946028)

**Registrant** - Prime Enterprises Inc. (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0257) , manufacture(58443-0257) , label(58443-0257) , analysis(58443-0257)

Revised: 1/2020

Prime Enterprises Inc.