

PANAMA JACK SPF 30- avobenzene, 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.

Active ingredients

Avobenzene 2 %, Homosalate 7.5 %, 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 our 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, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, Carrageenan, Citric Acid, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone,

Methylparaben, Oleth 10, Phenyl Trimethicone, Propylene Glycol, Propylparaben, Soluble Collagen, Sorbitan Oleate, Tocopheryl Acetate, Triethanolamine, Undecylcrylene Dimethicone, Water

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

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label



SPF 30

Spray Gel

SUNSCREEN

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

Contains Aloe Vera and Vitamin E

Non Greasy and Hypoallergenic

8 FL OZ (237 mL)

PANAMA JACK SPF 30

avobenzene, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0047
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.8 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	74.3 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)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
3-BUTYLPHTHALIDE (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
OLETH-10 (UNII: JD797EF70J)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W)	
WATER (UNII: 059QF0KO0R)	

SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0047-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/17/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0047) , pack(58443-0047) , manufacture(58443-0047) , analysis(58443-0047)

Revised: 1/2020

Prime Enterprises, Inc.