PANAMA JACK SPF 4 DARK TANNING OIL- octocrylene oil 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 4 SPF 4 Sunscreen Oil

Active Ingredients

Octocrylene 2%

Purpose

Sunscreen

Uses

• helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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. Keep away from face to avoid breathing it.

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

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- do not spray directly into face. Spray on hands then apply to face
- reapply:
- after swimming or sweating
- inmediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Extract, Arachis Hypogaea (Peanut) Oil, Citrus Medica Limonum (Lemon) Peel Oil, Cocos Nucifera (Coconut) Oil, Fragrance, Mineral Oil, Olea Europaea (Olive) Fruit Oil, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Theobroma Cacao (Cocoa) Seed Butter

Other Information

• protect this product from excessive heat and direct sun

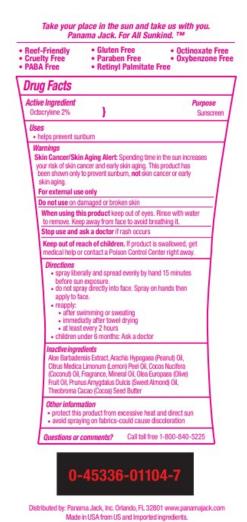
• avoid spraying on fabrics-could cause discoloration

Questions or comments?

Call toll free 1-800-840-5225

Panama Jack 4 SPF 4 Sunscreen Oil





PANAMA JACK SPF 4 DARK TANNING OIL

octocrylene oil

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0287
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	16.72 mg in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
LEMON OIL (UNII: 19 GRO 8 2 4 LL)				
ALMOND OIL (UNII: 66 YXD4DKO9)				
MINERAL OIL (UNII: T5L8T28FGP)				
COCOA BUTTER (UNII: 512OYT1CRR)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
COCONUT OIL (UNII: Q9L0O73W7L)				
PEANUT OIL (UNII: 5TL50QU0W4)				

Product Characteristics			
Color	yellow (Colorless to Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0287-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/04/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture (58443-0287), pack (58443-0287), label (58443-0287), analysis (58443-0287)

Revised: 1/2021 Prime Enterprises Inc.