

**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.*

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**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
- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

***Inactive Ingredients***

Aloe Barbadosis 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**



Take your place in the sun and take us with you.  
Panama Jack. For All Sunkind.™

- Reef-Friendly
- Cruelty Free
- PABA Free
- Gluten Free
- Paraben Free
- Retinyl Palmitate Free
- Octinoxate Free
- Oxybenzone Free

Drug Facts	
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<b>Uses</b> • helps prevent sunburn	
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<b>Questions or comments?</b> Call toll free 1-800-840-5225	

**0-45336-01104-7**

Distributed by: Panama Jack, Inc. Orlando, FL 32801 www.panamajack.com  
Made in USA from US and Imported ingredients.

**PANAMA JACK SPF 4 DARK TANNING OIL**

octocrylene oil

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0287
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	16.72 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
LEMON OIL (UNII: I9GRO824LL)	
ALMOND OIL (UNII: 66YXD4DKO9)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
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			

## Packaging

#	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.