

**PANAMA JACK SPF 4 DARK TANNING OIL- octinoxate 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 SPF 4 Dark Tanning Oil**

***Active Ingredients***

Octinoxate 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.

***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:
- at least every 2 hours
- children under 6 months: Ask a doctor

***Inactive Ingredients***

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

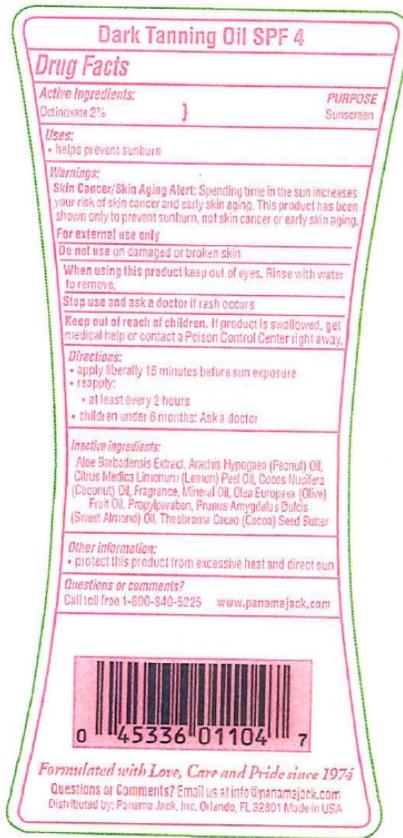
***Other Information***

- protect this product from excessive heat and direct sun

***Questions or comments?***

- Call toll free 1-800-840-5225 [www.panamajack.com](http://www.panamajack.com)

## Panama Jack SPF 4 Dark Tanning Oil



### PANAMA JACK SPF 4 DARK TANNING OIL

octinoxate oil

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0201
Route of Administration	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2 g in 100 g

#### Inactive Ingredients

Ingredient Name	Strength
PEANUT OIL (UNII: 5TL50QU0W4)	
LEMON OIL (UNII: I9GRO824LL)	
MINERAL OIL (UNII: T5L8T28FGP)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	

### 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:58443-0201-4	198.7 g in 1 BOTTLE; Type 0: Not a Combination Product	12/15/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/15/2011	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	manufacture(58443-0201) , pack(58443-0201) , label(58443-0201)

Revised: 1/2020

Prime Enterprises Inc.