

PALM ISLAND BROAD SPECTRUM SPF 50 SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene 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.

Palm Island Broad spectrum SPF 50 Sunscreen Lotion

Active Ingredients

Avobenzone 3.0%

Homosalate 15.0%

Octisalate 5.0%

Octocrylene 10.0%

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

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 value 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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Isodecyl Neopentanoate, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Water

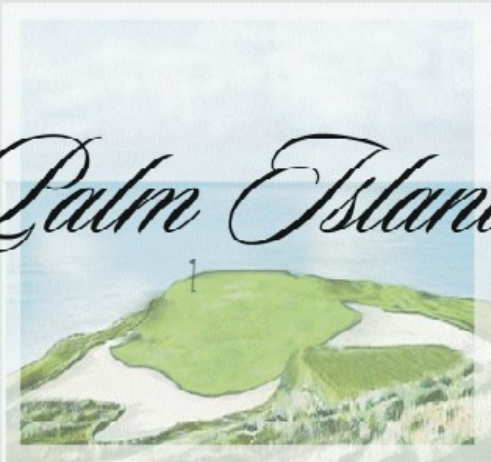
Other Information

- protect this container from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-274-8742 www.DuffysTriC.com

Palm Island Broad Spectrum SPF 50 Sunscreen Lotion



Palm Island

SUNSCREEN
LOTION
50

UVA/UVB SPF 50 BROAD SPECTRUM PROTECTION
FRAGRANCE-FREE

1 GALLON US / 128 Fl. Oz.

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3% Homosalate 15% Octisalate 5% Octocrylene 10%	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 a Broad Spectrum SPF value 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 of age: Ask a doctor	
Inactive Ingredients	
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Aluminum Starch Octenylsuccinate, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Isodecyl Neopentanoate, Phenoxyethanol, Polyethylene, Polysorbate 20, Propanediol, Sodium Hydroxide, Sorbitol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Trisodium Ethylenediamine Disuccinate, Water	
Other Information	
• protect this container from excessive heat and direct sun.	
Questions or Comments?	
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PALM ISLAND BROAD SPECTRUM SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0584
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	152.53 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.85 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	101.7 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.51 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ALLANTOIN (UNII: 344S277G0Z)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITOL (UNII: 506T60A25R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PROPANEDIOL (UNII: 5965N8W85T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	

Product Characteristics			
Color	white (off-white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0584-8	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2022	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		M020	02/10/2022	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0584) , manufacture(58443-0584) , label(58443-0584) , analysis(58443-0584)

Revised: 11/2022

Prime Enterprises Inc.