

**DESTINATION BRANDS INTERNATIONAL BROAD SPECTRUM SPF 50 SUNSCREEN-
avobenzone, homosalate, octisalate, octocrylene and oxybenzone 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.

Miami Beach Kids SPF 50 Broad Spectrum Lotion Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 3%

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 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, Aloe Barbadensis Leaf Juice, Beta-Carotene, Butylphthalimide, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Extract, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil,

Hydroxypropyl Methylcellulose, Isopropylphthalimide, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water (Aqua), Zea Mays (Corn) Oil

Other Information

- protect this product from excessive heat and direct sun
- may stain fabrics.

Questions or Comments?

Call 305.471.7989

Miami Beach Kids Broad Spectrum SPF 50 Sunscreen Lotion



Sunscreen Lotion
Broad Spectrum
SPF 50

UVA/UVB Protection
Water Resistant (80 Minutes)
Dye-Free, Fragrance-Free
Hypoallergenic For Sensitive Skin

Made with Blend of Natural
Marine Extracts

3 FL OZ (89 mL)



Take a little of MIAMI BEACH™ with you!

www.MiamiBeachSun.com

Drug Facts

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Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 2.75%, Oxybenzone 3%	Sunscreen

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Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadosensis Leaf Juice, Beta-Carotene, Butylphthalimide, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Extract, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

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Questions or comments?

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Made in USA

Distributed by: Destination Brands International
8600 NW 41 Street, Miami, Florida 33166

**Keep our beaches beautiful
Beach Cleanup Sponsorship**



DESTINATION BRANDS INTERNATIONAL BROAD SPECTRUM SPF 50 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0190
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	29.7 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	49.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	27.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TRICAPRIN (UNII: O1PB8EU98M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CORN OIL (UNII: 8470G57WFM)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
TOMATO (UNII: Z4KHF2C175)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H10UX5)	
CRAMBE MARITIMA LEAF (UNII: NO0DI2V62B)	

Product Characteristics

Color	orange	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0190-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/13/2015	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0190) , manufacture(58443-0190) , label(58443-0190)

Revised: 1/2020

Prime Enterprises Inc.