

MIAMI BEACH KIDS SUNSCREEN BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, 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.

Miami Beach Kids Sunscreen Lotion Broad Spectrum SPF 50

Active ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

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.

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 40 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

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Beta-Carotene, C12-15 Alkyl Benzoate, Carbomer, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopteroorgia Elisabethae Plant Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Styrene/Acrylates Copolymer, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

Other information

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

Miami Beach Kids Sunscreen Lotion Broad Spectrum SPF 50

Take a little of MIAMIBEACH™ with you!
www.MiamiBeachSun.com - @MBSuncare

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Made in USA From domestic and imported ingredients Distributed by: Destination Brands International P.O. Box 190586, Miami Beach, FL 33119. 305.592.8565	
Official suncare of the MIAMIBEACH™ Lifeguards	

6 FL OZ
177 mL

UVA/UVB Protection
Water Resistant (80 Minutes)
Dye-Free, Hypoallergenic
Dermatologist Tested

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MIAMI BEACH KIDS SUNSCREEN BROAD SPECTRUM SPF 50

avobenzene, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0256
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.76 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.6 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.28 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CORN OIL (UNII: 8470G57WFM)	
.BETA.-CAROTENE (UNII: 01YAE03M7J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SOLANUM LYCOPERSICUM FRUITING TOP (UNII: X636CG4BH0)	
ROSEMARY (UNII: IJ67X351P9)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	white (White to Off White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0256-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/15/2017	

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

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0256) , manufacture(58443-0256) , label(58443-0256) , analysis(58443-0256)

Revised: 1/2020

Prime Enterprises Inc.