

MIAMI BEACH SPF 50 KIDS C/S SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene spray
Prime Packaging 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 SPF 50 Kids C/S Sunscreen

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.

- keep away from face to avoid breathing it
- Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F

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
- reapply:
 - after 80 minutes of swimming and sweating
 - immediately after towel drying
 - at least every 2 hours
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in a well-ventilated area

- **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 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, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Caprylic/Capric Triglyceride, Crambe Maritima Extract, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Phenoxyethanol, Potassium Cetyl Phosphate, Propylene Glycol, Pseudopterogorgia Elisabethae Plant Extract, Sorbitol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water

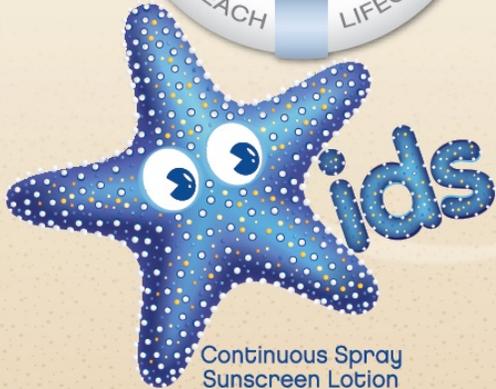
Other Information

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

Question or comments ?

Call 305.471.7989

Miami Beach SPF 50 C/S Sunscreen



Continuous Spray
Sunscreen Lotion
Broad Spectrum SPF 50

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

6 FL OZ
(177 mL)



Take a little of MIAMIBEACH™ with you!

Introducing our sensitive skin spray lotion made just for our littlest stars.
Made with ocean extracts for natural skin moisturizing
and sunscreen protection.

www.MiamiBeachSun.com

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75%	} Sunscreen
Uses	
<ul style="list-style-type: none"> helps prevent sunburn if used as directed with other sun protection measures (see <i>Directions</i>), 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.	
<ul style="list-style-type: none"> Keep away from face to avoid breathing it - Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°F. 	
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	
<ul style="list-style-type: none"> spray liberally and spread evenly by hand 15 minutes before sun exposure reapply: <ul style="list-style-type: none"> after 80 minutes of swimming or sweating immediately after towel drying at least every 2 hours hold container 4 to 6 inches from the skin to apply do not spray directly into face. Spray on hands then apply to face. do not apply in windy conditions use in a well-ventilated area 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 of 15 or higher and other sun protection measures including: <ul style="list-style-type: none"> 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 Copolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Caprylic/Capric Triglyceride, Crambe Maritima Extract, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Phenoxethanol, Potassium Cetyl Phosphate, Propylene Glycol, Pseudopterogorgia Elisabethae Plant Extract, Sorbitol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water	
Other information	
<ul style="list-style-type: none"> protect this product from excessive heat and direct sun. may stain fabrics. 	
Questions or comments?	
Call 305.471.7989	

Made in USA

Distributed by: Destination Brands International
P.O. Box 190586, Miami Beach, Florida 33119

Keep our beaches beautiful
Beach Cleanup Sponsorship



MIAMI BEACH SPF 50 KIDS C/S SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0103
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.27 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100.9 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50.45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	27.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CRAMBE MARITIMA LEAF (UNII: NO0DI2V62B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITOL (UNII: 506T60A25R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0103-4	177 mL in 1 CAN; Type 0: Not a Combination Product	02/29/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/29/2016	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0103) , analysis(13630-0103)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0103) , label(13630-0103)

Revised: 1/2020

Prime Packaging Inc.