

**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.*

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**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

Water (Aqua), Styrene/Acrylates Copolymer, Homosalate, Ethylhexyl Salicylate, Butyl Methoxydibenzoylmethane, Sorbitol, Octocrylene, Dimethicone, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Phenoxyethanol, Potassium Cetyl Phosphate, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Ethylhexylglycerin, Disodium EDTA, Tocopheryl Acetate, Butylphenyl Methylpropional, Aminomethyl Propanol, Aloe Barbadensis Leaf Juice, Hexyl Cinnamal, Linalool, Geraniol, Alpha-Isomethyl Ionone, Caprylic/Capric Triglyceride, Benzyl Salicylate, Propylene Glycol, Hydroxycitronellal, Limonene, Crambe Maritima Extract, Pseudopterogorgia Elisabethae Plant Extract

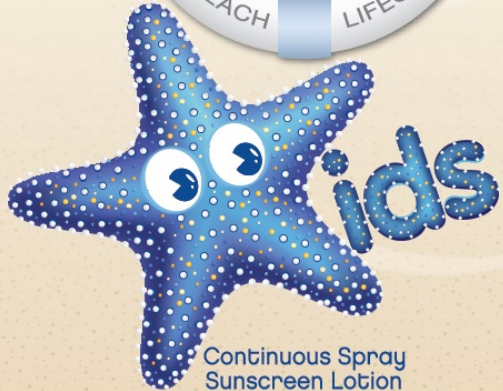
***Other Information***

- 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, Paraben Free  
Hypoallergenic For Sensitive Skin  
Dermatologist Tested  
With MB™ beach scent

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](http://www.MiamiBeachSun.com)

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75%	} Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• helps prevent sunburn</li> <li>• 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.</li> </ul>	
<b>Warnings</b>	
<b>For external use only</b>	
<b>Do not use</b> on damaged or broken skin	
<b>When using this product</b> 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.	
<b>Stop use and ask a doctor</b> if rash occurs	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• spray liberally and spread evenly by hand 15 minutes before sun exposure</li> <li>• reapply:               <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• hold container 4 to 6 inches from the skin to apply</li> <li>• do not spray directly into face. Spray on hands then apply to face.</li> <li>• do not apply in windy conditions</li> <li>• use in a well-ventilated area</li> <li>• 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"> <li>• limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> <li>• children under 6 months: Ask a doctor</li> </ul> </li> </ul>	
<b>Inactive ingredients</b>	
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, Fragrance, Phenoxethanol, Potassium Cetyl Phosphate, Propylene Glycol, Pseudopterogorgia (Isabathae Plant Extract, Sorbitol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun.</li> <li>• may stain fabrics.</li> </ul>	
<b>Questions or comments?</b>	
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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0104
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.66 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	102.2 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.1 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	28.11 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: NO0D12V62B)	
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: UDY3H10UX5)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
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:13630-0104-4	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(13630-0104) , analysis(13630-0104)

### Establishment

Name	Address	ID/FEI	Business Operations
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Prime Packaging Inc.		805987059	pack(13630-0104) , label(13630-0104)
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Revised: 1/2020

Prime Packaging Inc.