

**MIAMI BEACH SPORT SUNSCREEN 50 BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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 Sport Sunscreen Spray 50

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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

Flammable: Do not use near heat, flame, or while smoking.

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. • Do not puncture or incinerate. 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 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:

- 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/Octylacrylamide Copolymer, Fragrance, Propylene Glycol, Water, Pseudopterogorgia Elisabethae Plant Extract, SD Alcohol (Alcohol Denat.).

Other information

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

Question or comments?

Call 305.592.8565

Miami Beach Sport Sunscreen Spray 50

MIAMI BEACH™

SPORT SUNSCREEN SPRAY

50

Broad Spectrum SPF 50
UVA/UVB Protection

Water Resistant
(80 Minutes)

Fine Mist Spray

NET WT 5.5 OZ
(155 g)

Take a little of MIAMI BEACH™ with you!

Presenting our fine mist sport spray made with natural ocean extract, Sea Whip, and our refreshing M/B™ beach scent.

www.MiamiBeachSun.com - @MBSuncare

Drug Facts	
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Questions or comments?
Call 305.592.8365

Made in USA

From domestic and imported ingredients

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

Official sunscreen of the
MIAMI BEACH™ Lifeguards



MIAMI BEACH SPORT SUNSCREEN 50 BROAD SPECTRUM SPF 50

avobenzene, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0125
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	27 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	90 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	45 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	24.75 mg in 1 mL		
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	36 mg in 1 mL		
Inactive Ingredients				
Ingredient Name		Strength		
ALCOHOL (UNII: 3K9958V90M)				
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3HI0UX5)				
WATER (UNII: 059QF0K00R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK)				
Product Characteristics				
Color	yellow (Light Yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0125-4	177 mL in 1 CAN; Type 0: Not a Combination Product	03/13/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	03/13/2018		

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0125) , analysis(13630-0125)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	label(13630-0125) , pack(13630-0125)