MIAMI BEACH SEA SUNSCREEN 30 BROAD SPECTRUM SPF 30- 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 Sea Sunscreen Spray 30

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 eyes with water to remove. • Keep away from face to avoid breathing it. • Do not puncture or incinerate. Contents under pressure. 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

• inmediately 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 30

MIAMI BEACH SEA SUNSCREEN 30 BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0126
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	45 mg in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	24.75 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	36 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
WATER (UNII: 059QF0KO0R)	
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:13630-0126-4	177 mL in 1 CAN; Type 0: Not a Combination Product	03/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/15/2018	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0126) , analysis(13630-0126)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	label(13630-0126) , pack(13630-0126)

Revised: 1/2020 Prime Packaging Inc.