

MIAMI BEACH SEA SUNSCREEN BROAD SPECTRUM SPF 30- 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 Sea Sunscreen Lotion 30 Broad Spectrum SPF 30

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

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 80 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, Benzyl Alcohol, Caprylic/Capric Triglyceride, Chlorphenesin, Diethylhexyl Syringylidene-malonate, Disodium EDTA, Ethylhexyl Palmitate,

Fragrance, Fucus Serratus (Seaweed) Extract, Macrocystis Pyrifera (Kelp) Extract, Oleth-3, Palmaria Palmata (Algae) Extract, Polyamide-8, Propylene Glycol, Sodium Ascorbyl Phosphate, Sorbitol, Tocopherol, Triethanolamine, Water

Other information

- protect this product from excessive heat and direct sun.
- avoid contact with clothing to avoid staining.

Questions or comments?

Call 305.592.8565

Miami Beach Sea Sunscreen Lotion Broad Spectrum SPF 30

MIAMI BEACH™

SEA
SUNSCREEN LOTION

30

Broad Spectrum SPF 30
UVA/UVB Protection

Water Resistant
(80 Minutes)

Made with MB™
Triple Action Sea Kelp

5 FL OZ
148 mL

Take a little of MIAMIBEACH™ with you!

Presenting our paraben free, non-greasy triple action sea kelp sunscreen lotion. Infused with ocean extracts for natural skin moisturizing and protection.

www.MiamiBeachSun.com - @MBSuncare

Drug Facts

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Octisalate 5%	
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Made in USA

From domestic and imported ingredients

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

Official suncare of the
MIAMIBEACH™ Lifeguards



MIAMI BEACH SEA SUNSCREEN BROAD SPECTRUM SPF 30

avobenzene, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0260
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	99.6 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.88 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.8 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TROLAMINE (UNII: 9O3K93S3TK)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
OLETH-3 (UNII: BQZ26235UC)	
DULSE (UNII: 7832HOY4ZQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOMER 1342 (UNII: 809Y72KV36)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
FUCUS SERRATUS (UNII: V8K40WNW5B)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
MACROCYSTIS PYRIFERA (UNII: K31S3OG5C4)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
TOCOPHEROL (UNII: R0ZB2556P8)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0260-4	148 mL in 1 TUBE; Type 0: Not a Combination Product	03/27/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	03/27/2018	
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Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0260) , manufacture(58443-0260) , label(58443-0260) , analysis(58443-0260)

Revised: 1/2020

Prime Enterprises Inc.