MIAMI BEACH FACES SUNSCREEN 50 BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion Prime Enterprises Inc.

Miami Beach Faces Sunscreen Lotion 50

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.

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.

Other Information

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

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

Other information

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

Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Beta-Carotene, C12-15 Alkyl Benzoate, Caprylic/Capric Triglyceride, Carbomer, Crambe Maritima Leaf Extract, Dimethicone, Disodium EDTA, Ethylhexylglycerin, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Prunus Armeniaca (Apricot) Kernel Oil, Pseudopterogorgia Elisabethae Plant Extract, Rosmarinus Officinalis (Rosemarry) Leaf Extract, Sodium Hydroxide, Solanum Lycopersicum (Tomato) Fruit/Leaf/Stem Extract, Sorbitan Oleate, Styrene/Acrylates Copolymer, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Zea Mays (Corn) Oil

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avobenzone, homosalate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG Item Code (Source)		NDC:58443-0255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	29.76 mg in 1 mL		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.6 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.28 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.2 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER 1342 (UNII: 809Y72KV36)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CRAMBE MARITIMA LEAF (UNII: NO0DI2V62B)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
DIMETHICONE (UNII: 92RU3N3Y10)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CORN OIL (UNII: 8470G57WFM)	
.BETACAROTENE (UNII: 01YAE03M7J)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
PSEUDOPTEROGORGIA ELISABETHAE (UNII: UDY3H1OUX5)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
SOLANUM LYCOPERSICUM FRUITING TOP (UNII: X636CG4BH0)	
ROSEMARY (UNII: IJ67X351P9)	
COCOA BUTTER (UNII: 5120YT1CRR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics		
Color	white (White to Off White)	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging			
# Item Co	ode Package Des	scription Marketing S Date	Start Marketing End Date
1 NDC:58443 0255-3	- 118 mL in 1 TUBE; Type 0: Product	Not a Combination 03/09/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/09/2018	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0255) , manufacture(58443-0255) , label(58443-0255) , analysis (58443-0255)

Revised: 5/2024 Prime Enterprises Inc.