

SOLMATE BROAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene, and oxybenzone 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.

Active Ingredients

Avobenzone 2 %, Homosalate 7.5 %, Octisalate 5 %, Octocrylene 2.75 %, and Oxybenzone 2 %

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 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/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Fragrance, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene

Glycol, Propylparaben, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water


Other information

- protect this product from excessive heat and direct sun


❑ **Questions or Comments?:** Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, FL 33014

PRINCIPAL DISPLAY PANEL - 177 mL Bottle Label



SUNSCREEN LOTION



BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

SHEER NON-GREASY FORMULA

6 FL. OZ / 177mL

Drug Facts

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16363 NW 49 Avenue, Miami, FL 33014



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Distributed by: Biocycle Laboratories, Inc. | Miami, FL 33014

MADE IN USA

SOL

MATE

❑ Love the Sun

SUNSCREEN LOTION

30

BROAD SPECTRUM SPF 30
WATER RESISTANT (80 MINUTES)
SHEER NON-GREASY FORMULA
6 FL.OZ./177mL

SOLMATE BROAD SPECTRUM SPF 30 avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 443-0 110
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)		AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)		HOMOSALATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)		OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)		OCTOCRYLENE	27.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)		OXYBENZONE	20 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38 D8)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)			
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM8 3329)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J6 1HQ)			
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
EDETATE DISODIUM (UNII: 7FLD9 1C86 K)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
METHYL PARABEN (UNII: A2I8 C7HI9 T)			
HIGH DENSITY POLYETHYLENE (UNII: UG00 KM4WR7)			
POLYSORBATE 20 (UNII: 7T1F30 V5YH)			
PROPYLENE GLYCOL (UNII: 6DC9 Q167 V3)			
PROPYL PARABEN (UNII: Z8IX2SC1OH)			
SORBITAN MONOOLEATE (UNII: 06 XEA2VD56)			
COCOA BUTTER (UNII: 512O YT1CRR)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8 X80 D2L0)			
TROLAMINE (UNII: 9O3K93S3TK)			
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)			
WATER (UNII: 059 QF0 KO0 R)			
Product Characteristics			
Color	white	Score	

Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0110-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/19/2013	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final		part352	03/19/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Enterprises, Inc.		101946028	label(58443-0110) , pack(58443-0110) , manufacture(58443-0110) , analysis(58443-0110)	