

SOLMATE BROAD SPECTRUM SPF 15- avobenzone, octisalate, and 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.

Active Ingredients

Avobenzone 2 %, Octisalate 5 %, and Octocrylene 1.85 %

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 (Parfum), Hydroxypropyl Methylcellulose, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate,

Triethanolamine, Water (Aqua)

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

SOL MATE
Love the Sun

SUNSCREEN LOTION

15

BROAD SPECTRUM SPF 15

WATER RESISTANT (80 MINUTES)

SHEER NON-GREASY FORMULA

6 FL. OZ / 177mL

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Other information	
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Questions or Comments?: Biocycle Laboratories, Inc. 16363 NW 49 Avenue, Miami, FL 33014	

0 87524 96013 3

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

MADE IN USA

SOL

MATE

SUNSCREEN LOTION

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0105
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.86 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	49.65 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	18.3705 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38 D8)	
ALOE VERA LEAF (UNII: ZY8 1Z83H0 X)	
N-BUTYLPHTHALIMIDE (UNII: 5THIDKT35E)	
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: A2I8C7HI9 T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30 V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q 167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8 X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0105-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/28/2013	

Labeler - Prime Enterprises, Inc. (101946028)**Registrant** - Prime Enterprises, Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0105) , pack(58443-0105) , manufacture(58443-0105) , analysis(58443-0105)

Revised: 1/2020

Prime Enterprises, Inc.