

## **SOLMATE BROAD SPECTRUM SPF 8- avobenzone, 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.*

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### **Active ingredients**

Avobenzone 1%, Octisalate 3%, Octocrylene 0.85%, and Oxybenzone 1%

### **Purpose**

Sunscreen

### **Uses**

- helps prevent sunburn

### **Warnings**

**Skin Cancer/ Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. this product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

### **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**

**8**

**BROAD SPECTRUM SPF 8**

**WATER RESISTANT (80 MINUTES)**

**SHEER NON-GREASY FORMULA**

**6 FL. OZ / 177mL**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 1% Octisalate 3% Octocrylene 0.85% Oxybenzone 1%	Sunscreen
<b>Uses</b>	
■ helps prevent sunburn	
<b>Warnings</b>	
<b>Skin Cancer/Skin Aging Alert:</b> Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, <b>not</b> skin cancer or early skin aging.	
<b>For external use only</b>	
<b>Do not use</b> on damaged or broken skin	
<b>When using this product</b> keep out of eyes. Rinse with water to remove.	
<b>Stop use and ask a doctor</b> if rash occurs	
<b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
■ apply liberally 15 minutes before sun exposure	
■ reapply:	
• after 80 minutes of swimming or sweating	
• immediately after towel drying	
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<b>Inactive ingredients</b>	
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)	
<b>Other information</b>	
■ protect this product from excessive heat and direct sun	
<b>Questions or Comments?:</b> Biocycle Laboratories, Inc. 16363 NW 49 Avenue, Miami, FL 33014	

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

MADE IN USA

0 87524 96017 1

**SOL**

**MATE**

*Love the Sun*

**SUNSCREEN LOTION**

**BROAD SPECTRUM SPF 8****WATER RESISTANT (80 MINUTES)****SHEER NON-GREASY FORMULA****6 FL.OZ/ 177mL****SOLMATE BROAD SPECTRUM SPF 8**

avobenzone, octisalate, octocrylene, and oxybenzone lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0104
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9.94 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8.449 mg in 1 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	9.94 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	29.84 in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>(C10-C30)ALKYL METHACRYLATE ESTER</b> (UNII: XH2FQZ38D8)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>N-BUTYLPHTHALIMIDE</b> (UNII: 5TH1DKT35E)	
<b>ISOPROPYLPHTHALIMIDE</b> (UNII: 1J1MM83329)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 4Q93RCW27E)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBITAN MONOLEATE</b> (UNII: 06XEA2VD56)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0104-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/28/2013	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0104) , pack(58443-0104) , manufacture(58443-0104) , analysis(58443-0104)

Revised: 1/2020

Prime Enterprises, Inc.