

SOLMATE KIDS BROAD SPECTRUM SPF 50- 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 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 2.75 %, and Oxybenzone 3 %

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 Tube Label

SOLMATE
KID'S
SUNSCREEN
LOTION

50

BROAD SPECTRUM SPF 50
WATER RESISTANT (80 MINUTES)
NON-GREASY FORMULA

6 FL. OZ / 177mL

Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75% Oxybenzone 3%	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

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

MADE IN USA

0 87524 96018 8

SOLMATE

KID'S

SUNSCREEN

LOTION

50

BROAD SPECTRUM SPF 50

WATER RESISTANT (80 MINUTES)

NON-GREASY FORMULA

6 FL.OZ./177mL

SOLMATE KIDS BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0115
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	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		OCTOCRYLENE	275 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)		OXYBENZONE	30 mg in 1 mL
Inactive Ingredients			
Ingredient Name			Strength
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)			
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)			
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)			
COCOA BUTTER (UNII: 512OYT1CRR)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
TROLAMINE (UNII: 9O3K93S3TK)			
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)			
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:58443-0115-4	177 mL in 1 TUBE; 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(58443-0115) , pack(58443-0115) , manufacture(58443-0115) , analysis(58443-0115)