SOLMATE BROAD SPECTRUM SPF 8- avobenzone, octisalate, octocrylene, and oxybenzone aerosol, spray Prime Packaging, 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 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 skin aging. This product has been shown only to prevent sunburn, **not** liskin cancer or early skin aging.

For external use only

Do not use Ion damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

- •Keep away from face to avoid breathing it.
- •Contents under pressure-do not puncture or incinerate. Do not store at temperatures above 120°F

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.

Flammable: Do not use near heat, flame or while smoking.

Directions

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face.
- do not apply in windy conditions
- use in a well-ventilated area
- reapply:
- After 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

C12-15 Alkyl Benzoate, Fragrance (Parfum), SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer

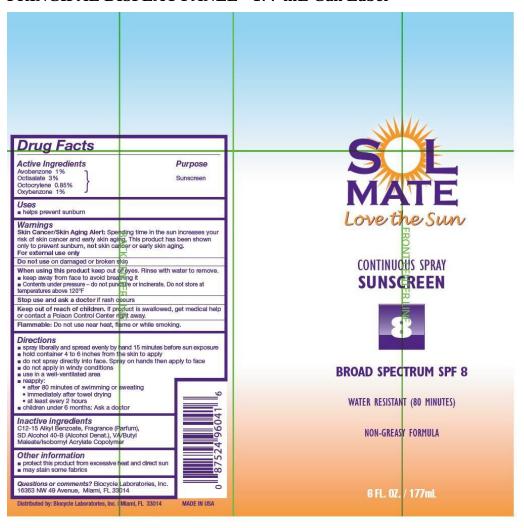
Other Information

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

Questions or comments? Biocycle Laboratories, Inc.

16363 NW 49 Avenue, Miami, Fl 33014

PRINCIPAL DISPLAY PANEL - 177 mL Can Label



Love the Sun

Continuous Spray

Sunscreen

8

Broad Spectrum SPF 8

Water Resistant (80) Minutes

Non-Greasy Formula

SOLMATE BROAD SPECTRUM SPF 8

avobenzone, octisalate, octocrylene, and oxybenzone aerosol, spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0075	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	8.1 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	24.3 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6.885 mg in 1 mL		
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	8.1 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
ALKYL (C12-15) BENZO ATE (UNII: A9EJ3J61HQ)			
ALCOHOL (UNII: 3K9958V90M)			
BUTYL MALEURATE (UNII: 6FUA0H660I)			
ISOBORNYL ACRYLATE (UNII: IX0 PRH184P)			

Product Characteristics			
Color	yello w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Ш	Packaging			
Ш	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:13630-0075-4	177 mL in 1 CAN; Type 0: Not a Combination Product	0 3/0 1/20 15	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	0 3/0 1/20 15	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	analysis(13630-0075), manufacture(13630-0075)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0075), pack(13630-0075)

Revised: 1/2020 Prime Packaging, Inc.