SOLMATE BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene and oxybenzone 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.

SolMate Baby Continuous Spray Sunscreen Lotion 50

Active Ingredients

Avobenzone 3 %

Homosalate 10 %

Octisalate 5 %

Octocrylene 2.75 %

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.

- keep away from face to avoid breathing it.
- Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120 ^{0}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.

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 well-ventilated areas.
- 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 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, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Aminomethyl Propanol, Butylphthalimide, Chamomilla Recutita (Matricaria) Flower Extract, Disodium EDTA, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Potassium Cetyl Phosphate, Propylene Glycol, Propylparaben, Sorbitol, Styrene/Acrylates Copolymer, Tocopheryl Acetate, Water

Other information

- protect this product from excesive heat and direct sun
- may stain some fabrics

Questions or Comments?:

Biocycle Laboratories, Inc.

16363 NW 49th Avenue, Miami, FL 33014

SolMate Baby Continuous Spray Sunscreen Lotion 50

SOLMATE BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene and oxybenzone spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0136
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	27.225 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHAMOMILE (UNII: FGL3685T2X)	
WATER (UNII: 059QF0KO0R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0136-5	255 mL in 1 CAN; Type 0: Not a Combination Product	03/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/07/2018	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0136) , analysis(13630-0136)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0136) , pack(13630-0136)

Revised: 1/2020

Prime Packaging, Inc.