SOLMATE BROAD SPECTRUM SPF 50 C/S SUNSCREEN- avobenzone, homosalate, octisalate, oxybenzone and octocrylene 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 Sport SPF 50 C/S Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 4%

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°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 and 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

Fragrance (Parfum), SD Alcohol 40-B (Alcohol Denat.), Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other Information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics could cause discoloration

Question or comments?

Biocycle Laboratories, Inc. 16363 NW 49 Avenue, Miami, FL 33014

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avobenzone, homosalate, octisalate, oxybenzone and octocrylene spray

| Product Information | | | | |
|-------------------------|----------------|--------------------|----------------|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13630-0100 | |
| Route of Administration | TOPICAL | | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|------------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 25.5 mg in 1 mL | | |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 85 mg in 1 mL | | |
| OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 42.5 mg in 1 mL | | |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 23.38 mg in 1 mL | | |
| OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 34 mg in 1 mL | | |

| Inactive Ingredients | | | | |
|--|----------|--|--|--|
| Ingredient Name | Strength | | | |
| .ALPHATO CO PHERO L ACETATE (UNII: 9E8 X80 D2L0) | | | | |
| ALCOHOL (UNII: 3K9958V90M) | | | | |
| DIBUTYL MALEATE (UNII: 4X371TMK9K) | | | | |

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

| | P | ackaging | | | |
|---|---|------------------|--|-----------------------------|---------------------------|
| l | # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| l | 1 | NDC:13630-0100-4 | 177 mL in 1 CAN; Type 0: Not a Combination Product | 02/01/2016 | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part352 | 0 2/0 1/20 16 | |
| | | | |

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

| Establishment | | | |
|-----------------------|---------|---------------|---|
| Name | Address | ID/FEI | Business Operations |
| Prime Enterprises Inc | | 10 19 46 0 28 | manufacture(13630-0100), analysis(13630-0100) |

| Establishment | | | | |
|----------------------|---------|-----------|-------------------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Prime Packaging Inc. | | 805987059 | pack(13630-0100), label(13630-0100) | |

Revised: 1/2020 Prime Packaging Inc.