

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** 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.

- 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

| Drug Facts | |
|--|-----------------------------|
| Active Ingredients Avobenzone 1% Octisalate 3% Octocrylene 0.85% 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. ■ 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: <ul style="list-style-type: none">• 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 some fabrics | |
| Questions or comments? Biocycle Laboratories, Inc. 16363 NW 49 Avenue, Miami, FL 33014 | |

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

SOL

MATE

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 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W) | OCTISALATE | 24.3 mg in 1 mL |
| OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE | 6.885 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y) | OXYBENZONE | 8.1 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| BUTYL MALEURATE (UNII: 6FUA0H660I) | |
| ISOBORNYL ACRYLATE (UNII: IX0PRH184P) | |

Product Characteristics

| | | | |
|----------|--------|--------------|--|
| Color | yellow | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | 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 | 03/01/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 03/01/2015 | |

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.