

SOLEIL TOUJOURS SPF 30 SHEER SUNSCREEN MIST- avobenzone, homosalate, octisalate 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.

Soleil Toujours Broad Spectrum SPF 30 Sheer Sunscreen Mist

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

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.

Flammable: Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120°F. Do not use in the presence of a flame or spark, or while smoking.

Do not use on damaged or broken skin.

When using this product keep away from face to avoid breathing in. 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

- **Shake well**
- Hold container 4 to 6 inches from the skin to apply
- Apply liberally 15 minutes before sun exposure

- 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
- **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

Other Information

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

Aloe Barbadensis Leaf Juice, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Cucumis Sativus (Cucumber) Extract, Fragrance, Glycerin, Polyester-8, Porphyra Umbilicalis Extract, SD Alcohol 40-B, Sodium Hyaluronate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water

Question or comments?

Call 1-877-320-2381 www.soleiltoujours.com

Soleil Toujours SPF 30 Sheer Sunscreen Mist - 170 g

SOLEIL TOUJOURS

30

**CLEAN CONSCIOUS
ANTIOXIDANT SUNSCREEN MIST**
BROAD SPECTRUM SPF 30
WATER RESISTANT (80 MINUTES)
70%+ ORGANIC

NET WT 6.0 OZ (170 g)

ALWAYS LUXURIOUS. NEVER HARMFUL.
CORAL REEF SAFE, VEGAN, GLUTEN FREE,
PARABEN FREE, ANTI-AGING, ECO FRIENDLY PACKAGING

ONE SUN. ONE LOVE.™
A portion of our proceeds support coral reef restoration at GoldenEye, Jamaica.

Drug Facts

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|---|-----------|
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Inactive ingredients Aloe Barbadensis Leaf Juice, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Cucumis Sativus (Cucumber) Extract, Fragrance, Glycerin, Polyester-8, Porphyra Umbilicalis Extract, SD Alcohol 40-B, Sodium Hyaluronate, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water

Questions or Comments? Call 1-877-320-2381 www.soleiltoujours.com

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60003 75206 7

NO CFCs

12M

Backgrounds Bleed Through Outside Dimensions

Copy Limit
Height: 128 mm
Width: 157 mm

SOLEIL TOUJOURS SPF 30 SHEER SUNSCREEN MIST

avobenzone, homosalate, octisalate spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:13630-0210 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 24.9 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 62.25 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 41.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|--|--|
| POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| PORPHYRA UMBILICALIS (UNII: 14AN0J70WO) | |
| WATER (UNII: 059QF0KO0R) | |
| ASCORBYL PALMITATE (UNII: QN83US2B0N) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CUCUMBER (UNII: YY7C30VXJT) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| LEVOMENOL (UNII: 24WE03BX2T) | |

Product Characteristics

| | | | |
|-----------------|-----------------------|---------------------|--|
| Color | yellow (Light Yellow) | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:13630-0210-4 | 205 mL in 1 CAN; Type 0: Not a Combination Product | 04/26/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 04/26/2021 | |

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|---|
| Prime Enterprises Inc | | 101946028 | analysis(13630-0210) , manufacture(13630-0210) , label(13630-0210) , pack(13630-0210) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|--------------------------------------|
| Prime Packaging Inc. | | 805987059 | pack(13630-0210) , label(13630-0210) |

