

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.

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.

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.

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 - 85 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.

SOLEIL TOUJOURS

30
CLEAN CONSCIOUS
ANTIOXIDANT SUNSCREEN MIST
BROAD SPECTRUM SPF 30
WATER RESISTANT (80 MINUTES)
70%+ ORGANIC
NET WT 3.0 OZ (85 g)

Drug Facts

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Directions Shake well • Hold container 4 to 6 inches from 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 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.

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Inactive ingredients Aloe Barbadosensis 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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NO CFCS
12M

Barcode: 60003 75207 4

SOLEIL TOUJOURS SPF 30 SHEER SUNSCREEN MIST

avobenzone, homosalate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0211
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: WZZU1RY8B0)	
.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:13630-0211-3	102 mL in 1 CAN; Type 0: Not a Combination Product	04/28/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/28/2021	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	analysis(13630-0211) , manufacture(13630-0211) , label(13630-0211) , pack(13630-0211)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0211) , label(13630-0211)