

SOLEIL TOUJOURS SPF 50 SHEER SUNSCREEN- 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 SPF 50 Sheer Sunscreen Mist

Active Ingredients

Avobenzone 3%, Homosalate 10%, 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 skin to apply.
- Apply liberally 15 minutes before sun exposure
- Do not spray directly into face
- **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.

Other information

- Protect this product from excessive heat and direct sun. Avoid spraying on fabrics - could cause discoloration.

Inactive ingredients

Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Fragrance, Glycerin, Polyester-8, Porphyra Umbilicalis Extract, SD Alcohol 40-B, 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 50 Sheer Sunscreen Mist



SOLEIL TOUJOURS

50

**CLEAN CONSCIOUS
ANTIOXIDANT SUNSCREEN MIST**
BROAD SPECTRUM SPF 50
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	Purpose
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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	
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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 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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Questions or Comments? Call 1-877-320-2381 www.soleiltoujours.com	

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Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0209
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.2 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	84 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		

PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
LEVOMENOL (UNII: 24WE03BX2T)	
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

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:13630-0209-4	202 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	manufacture(13630-0209) , analysis(13630-0209)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0209) , label(13630-0209)