

SOLEIL TOUJOURS SPF 15 SHEER SUNSCREEN- avobenzone, 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 15 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** • apply liberally 15 minutes before sun exposure
- **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

Inactive ingredients

Artemesia Pallens Flower Oil, Aloe Barbadosensis Leaf Juice, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Citrus Aurantifolia Peel Oil, Citrus Aurantium Bergamia Fruit Extract, Citrus Limon Peel Oil, Citrus Nobilis Flower Oil, Citrus Sinensis Peel Oil, Cucumis Sativus (Cucumber) Extract, Ethyl Acetate, Ethyl Acetoacetate, Ferula Galbaniflua Resin Oil, Gamma Undecalactone, Glycerin, Heliotropine, Isoamyl Acetate, Isobutyl Acetate, Jasminum

Sambac Oil, Opoponax Oil, Polyester-8, Porphyra Umbilicalis Extract, Salvia Sclarea Oil, SD Alcohol 40-B, Sodium Hyaluronate, Tetrahexyldecyl Ascorbate, Tocopherol, Tocopheryl Acetate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water

Other information

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

Question or comments?

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

Soleil Toujours SPF 15 Sheer Sunscreen Mist

Powerful sun care meets powerful skin care. Protect your skin from harmful UVA/UVB rays with this broad spectrum sheer sunscreen. Our formula uses 70%+ organic ingredients plus our proprietary EcoSun Complex® (Red Algae, Vitamin C Ester, Vitamin E & Bisabolol), other potent antioxidants and anti-aging actives to hydrate and nourish the skin. 80 minutes water resistant, this sunscreen is ideal for sports and the active lifestyle. Environmentally friendly continuous mist works from any angle. 100% natural fragrance. NO: oxybenzone, octinoxate, retinyl palmitate, parabens, propylene glycol, sodium lauryl sulfate, synthetic fragrance or color.

Drug Facts

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Avobenzone 2%, Octisalate 5%	Sunscreen

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DISTRIBUTED BY:
Soleil Toujours, LLC, Bronville, NY 10708
Energie 43, 1271 EC, Huizen, Netherlands

MADE IN U.S.A.

TC/DOT-2P © 5703

NO CFCS

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SOLEIL TOUJOURS SPF 15 SHEER SUNSCREEN

avobenzone, octisalate spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0133
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.52 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	41.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LEVOMENOL (UNII: 24WE03BX2T)	
GALBANUM OIL (UNII: 211UF7M8N1)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
OPOPANAX RESIN (UNII: TA8L57B94W)	
ORANGE OIL (UNII: AKN3KSD11B)	
BERGAMOT OIL (UNII: 39W1PKE3J1)	
DAVANA OIL (UNII: CL439Y041G)	
WATER (UNII: 059QF0KO0R)	
ALCOHOL (UNII: 3K9958V90M)	
.GAMMA.-UNDECALACTONE (UNII: QB1T0AG2YL)	
PIPERONAL (UNII: KE109YAK00)	
ISOBUTYL ACETATE (UNII: 7CR47FO6LF)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOAMYL ACETATE (UNII: Z135787824)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CUCUMBER JUICE (UNII: 61845009SP)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL ACETATE (UNII: L9MK238N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CLARY SAGE OIL (UNII: 87L0D4U3M0)	
ETHYL ACETOACETATE (UNII: IZP61H3TB1)	
LEMON OIL (UNII: I9GRO824LL)	
LIME OIL (UNII: UZH29XGA8G)	
CITRUS NOBILIS (UNII: 8MFF77J91V)	
JASMINUM SAMBAC WHOLE (UNII: 1Z81V275I0)	
ETHYL ACETATE (UNII: 7684508NMZ)	

Product Characteristics

Color	yellow (Colorless to Pale Yellow)	Score	
Shape		Size	

Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0133-4	177 mL in 1 CAN; Type 0: Not a Combination Product	04/13/2017	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	04/13/2017		

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0133) , analysis(13630-0133)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0133) , label(13630-0133)