

**SOLEIL TOUJOURS SPF 50 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 Face and Scalp Sunscreen Mist Broad Spectrum SPF 50

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.

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 it. Do not store at temperatures above 120°F.

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.

Abies Siberica Needle Oil, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Citrus Aurantifolia Fruit Oil, Citrus Aurantium Bergamia Fruit Extract, Citrus Aurantium Dulcis Peel Oil, Citrus Grandis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Reticulata Leaf Oil, Commiphora Myrrha Resin Oil, Ethyl Vanillin, Eucalyptus Globulus Leaf Oil, Ferula Galbaniflua Oil, Glycerin, Juniperus virginiana Oil, Lavandula Angustifolia Oil, Mentha Piperita Stem/Leaf Oil, Mentha

Viridis Leaf Oil, Myristica Fragrans Kernel Oil, Pelargonium Graveolens Flower Oil, Pogostemon Cablin Oil, Polyester-8, Porphyra Umbilicalis Extract, Rosa Damascena Flower Oil, Salvia Sclarea Oil, Santalum Spicata Wood Oil, SD Alcohol 40-B, Tetrahexyldecyl Ascorbate, Thymus Vulgaris Oil, Tocopheryl Acetate, Triethyl Citrate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Vanillin, Water

Directions

- Shake well before use
- with your eyes completely closed, mist face evenly, holding bottle 10-12 inches away from face. Do not breath mist in,Allow to fully dry.
- apply liberally 15 minutues before sun exposure
- **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

Question or comments?

Call 1-877-320-2381

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Drug Facts

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Homosalate 10%
Octisalate 5%

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Uses

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Warnings

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. Stop use and ask a doctor if rash occurs. Keep away from face to avoid breathing it. Contents under pressure – do not puncture or incinerate. Do not store at temperatures above 120°F.

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.

Inactive Ingredients

Abies Siberica Needle Oil, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Citrus Aurantifolia Fruit Oil, Citrus Aurantium Bergamia Fruit Extract, Citrus Aurantium Dulcis Peel Oil, Citrus Grandis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Reticulata Leaf Oil, Commiphora Myrrha Resin Oil, Ethyl Vanillin, Eucalyptus Globulus Leaf Oil, Ferula Galbaniflua Oil, Glycerin, Juniperus virginiana Oil, Lavandula Angustifolia Oil, Mentha Piperita Stem/Leaf Oil, Mentha Viridis Leaf Oil, Myristica Fragrans Kernel Oil, Pelargonium Graveolens Flower Oil, Pogostemon Cablin Oil, Polyester-8, Porphyra Umbilicalis Extract, Rosa Damascena Flower Oil, Salvia Sclarea Oil, Santalum Spicata Wood Oil, SD Alcohol 40-B, Tetrahexyldecyl Ascorbate, Thymus Vulgaris Oil, Tocopheryl Acetate, Triethyl Citrate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Vanillin, Water

Drug Facts (continued)

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 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses
 - children under 6 months: Ask a doctor.

Other Information

- Protect the product in this container from excessive heat and direct sunlight.

Questions or comments?

Call 1-877-320-2381

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SOLEIL TOUJOURS

EXTRÈME FACE + SCALP SUNSCREEN MIST

BROAD SPECTRUM
SPF 50
WATER RESISTANT
(80 MINUTES)

REEF SAFE ORGANIC

SPORT 50

2 FL OZ e 59 mL

*Beautiful skin deserves
powerful protection.*

Our sport-strength lightweight mist protects delicate skin on the face and scalp. Made with 70%+ organic ingredients and power-packed with our EcoSun Complex®, this mist provides sheer broad spectrum UV protection. The perfect defense for an active lifestyle.



EcoSun Complex® is our proprietary antioxidant blend and the secret weapon found in all our products. **Red Algae, Bisabolol, Vitamin C Ester & Vitamin E** help to scavenge free radicals, reduce UV induced damage, and increase skin smoothness and brightness.



NO OXYBENZONE OR OCTINOXATE
100% NATURAL FRAGRANCE
PARABEN FREE
SILICONE FREE
GLUTEN FREE
ANTI-AGING



SOLEILTOUJOURS.COM

SOLEIL TOUJOURS SPF 50 SUNSCREEN MIST

avobenzone, homosalate, octisalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0200
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	83.9 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: ROZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
WATER (UNII: 059QF0KO0R)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
LEVOMENOL (UNII: 24WE03BX2T)	
VINYL ACETATE (UNII: L9MK238N77)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	

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:13630-0200-3	59 mL in 1 CAN; Type 0: Not a Combination Product	06/26/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/26/2020	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0200) , analysis(13630-0200)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0200) , label(13630-0200)

Revised: 11/2021

Prime Packaging Inc.