SOLEIL TOUJOURS BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate lotion Prime Enterprises 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 Toujors Set + Protect Micro Mist Broad Spectrum SPF 30 Sunscreen

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 us **e** 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.

Directions

- shake well before use
- with your eyes completely closed, mist face evenly, holding bottle 10-12 inches away from face. Do not breathe mist in. Allow to fully dry.
- apply liberally 15 minutes 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 broad spectrum SPF value 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Abies siberica Needle Oil, Aloe Barbadensis Leaf Juice, 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, Cucumis Sativus (Cucumber) Extract, 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, Sodium Hyaluronate, Tetrahexyldecyl Ascorbate, Thymus vulgaris Oil, Tocopheryl Acetate, Triethyl Citrate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Vanillin, Water

Other Information

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

Question or comments?

Call 1-877-320-2381

Soleil Toujours Set + Protect Micro Mist Broad Spectrum SPF 30 SPF 30 Sunscreen



Drug Facts

Active Ingredients

Purpose

directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging

Warnings For external use only

When using this product keep out of eyes.

Keep out of reach of children. If product is

Flammable: Do not use near heat, flame or

Inactive Ingredients

Inactive Ingredients

Abies Siberica Needle Oil, Aloe Barbadensis Leaf Auice, Ascorbyl Palmitate, Bisabolol, Camellia Oleifera (Green Tea) Leaf Extract, Caprylic/Capric Triglyceride, Citrus Aurantifolia Fruit Oil, Citrus Aurantifum Dukis Peel Oil, Citrus Aurantifum Dukis Peel Oil, Citrus Robilis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Limon Peel Oil, Citrus Nobilis Peel Oil, Citrus Limon Peel Oil, Commiphora Myrrha Resin Oil, Cucumis Sativus (Cucumber) Extract, Ethyl Vanillin, Eucolyptus Globulus Leaf Oil, Fernia Galbaniflua Oil, Glycerin, Juniperus Virginiana Oil, Lavandula Angustifolia Oil, Mentha Piperita Stem/Leaf Oil, Mentha Viridis Leaf Oil, Myristica Fragrans Kemel 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 Akohol 40-8, Sodium Hyaluronate, Teetrahexylderyl Ascorbate, Thymus Vulgaris Oil, Tocopheryl Acetate, Triethyl Citrate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Vanillin, Water

Drug Facts (continued)

Directions

- shake well before use
 with your eyes completely closed, mist face evenly, holding bottle 10-12 inches away from face. Do not breathe mist in. Allow to fully dry. • apply liberally 15 minutes before sun
- · reapply:

- 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 value of 15 or higher and other sun protection measures including:

Other Information

Questions or comments?







TOUJOURS®

BROAD SPECTRUM

SET + PROTECT MICRO MIST

BROAD SPECTRUM SPF 30 WATER RESISTANT (80 MINUTES)

> ORGANIC REEF SAFE

Beautiful skin deserves



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

Green Tea Leaf Extract

Sodium Hyaluronate

Aloe Leaf Juice





SOLEILTOUJOURS.COM

SOLEIL TOUJOURS BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate lotion

Product Information

HUMAN OTC DRUG NDC:58443-0555 **Product Type** Item Code (Source)

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.3 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	24.78 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	24.78 mg in 1 mL	

Ingredient Name	Strength		
BERGAMOT OIL (UNII: 39W1PKE3JI)	Strength		
ORANGE PEEL (UNII: TI9T76XD44)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
GLYCERIN (UNII: PDC6A3C0OX)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
WATER (UNII: 059QF0KO0R)			
LEMON OIL, COLD PRESSED (UNII: 19GRO824LL)			
CITRUS NOBILIS (UNII: 8MFF77 91V)			
LEVOMENOL (UNII: 24WE03BX2T)			
CITRUS AURANTIIFOLIA FRUIT OIL (UNII: 7937R189CB)			
CITRUS MAXIMA FRUIT RIND OIL (UNII: 8U3877WD44)			
CITRUS RETICULATA LEAF OIL (UNII: 1515UE78IH)			
SPEARMINT OIL (UNII: C3M81465G5)			
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)			
SANTALUM SPICATUM OIL (UNII: H9LVS6REV4)			
ALCOHOL (UNII: 3K9958V90M)			
TRIETHYL CITRATE (UNII: 8Z 96QXD6UM)			
VANILLIN (UNII: CHI530446X)			
MENTHA PIPERITA LEAF (UNII: A389O33LX6)			
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)			
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)			
THYME OIL (UNII: 2UK410MY6B)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
GALBANUM OIL (UNII: 211UF7M8N1)			
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)			
LAVENDER OIL (UNII: ZBP1YXW0H8)			
MYRRH OIL (UNII: H74221J5J4)			
CUCUMBER (UNII: YY7C30VXJT)			
EUCALYPTUS OIL (UNII: 2R040Ni662)			
ROSA DAMASCENA FLOWER OIL (UNII: 18920M3T13)			
CLARY SAGE OIL (UNII: 87L0D4U3M0)			
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)			
ABIES SIBIRICA WHOLE (UNII: 80YP21OD21)			
ETHYL VANILLIN (UNII: YC9ST449YJ)			
NUTMEG OIL (UNII: Z1CLM48948)			
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)			
HYALURONATE SODIUM (UNII: YSE9PPT4TH)			

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

Product Characteristics			
Color	yellow (Very Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:58443- 0555-3	59 mL in 1 TUBE; Type 0: Not a Combination Product	02/20/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/20/2017	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0555) , manufacture(58443-0555) , label(58443-0555) , analysis (58443-0555)

Revised: 8/2022 Prime Enterprises Inc.