

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 Toujours Makeup Setting Spray SPF 30 Broad Spectrum 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 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 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 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

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 this product from excessive heat and direct sun.

Question or comments?

Call 1-877-320-2381

Soleil Toujours SPF 30 Makeup Setting Spray Sunscreen

DRUG FACTS

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Homosalate 7.5%,
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www.soleiltoujours.com

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Inactive Ingredients
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 Cabilin 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

SOLEIL TOUJOURS
Front

6.4687

30

CLEAN CONSCIOUS SET + PROTECT MICRO MIST
BROAD SPECTRUM SUNSCREEN SPF 30
WATER RESISTANT (80 MINUTES)
70%+ ORGANIC
1.7 FL OZ e 50 ML

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 supports coral reef restoration at GoldenEye, Jamaica.

Protect delicate skin on the face and set makeup with 70%+ organic, sheer, broad spectrum UV protection. Water & sweat resistant, this weightless finishing mist leaves a matte appearance and keeps makeup looking fresh. Hydrating, lightweight, non greasy, & fast-drying. Effortlessly re-apply throughout the day.

Antioxidant rich
Green Tea Leaf Extract
Sodium Hyaluronate
Cucumber Extract
Aloe Leaf Juice
Water Resistant (80 Minutes)

SOLEIL TOUJOURS BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0518
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.85 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.11 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	62.78 mg in 1 mL
Inactive Ingredients		
Ingredient Name	Strength	
BERGAMOT OIL (UNII: 39W1PKE3JI)		
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: I9GRO824LL)		
CITRUS NOBILIS (UNII: 8MFF77J91V)		
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: 8Z96QXD6UM)		
VANILLIN (UNII: CHI530446X)		
MENTHA PIPERITA LEAF (UNII: A389O33LX6)		
POGOSTEMON CABLIN LEAF OIL (UNII: F3IN55X5PO)		
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)		
THYME OIL (UNII: 2UK410MY6B)		
.ALPHA.-TOCOPHEROL 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: 2R04ONI662)		
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)		
ASCORBYL PALMITATE (UNII: QN83US2B0N)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0518-3	50 mL in 1 TUBE; Type 0: Not a Combination Product	08/30/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/30/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0518) , manufacture(58443-0518) , label(58443-0518) , analysis(58443-0518)

Revised: 1/2022

Prime Enterprises Inc.