

SOLEIL TOUJOURS PERPETUAL RADIANCE BROAD SPECTRUM SPF 20- titanium dioxide and zinc oxide 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.

Active ingredients

Titanium Dioxide 1.8 % and Zinc Oxide 4.2 %

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

Inactive Ingredients

Acrylates Copolymer, Algin, Aloe Barbadensis Leaf Juice, Alumina, Aluminum Hydroxide, Argania Spinosa Kernel Oil, Ascorbyl Palmitate, Beeswax, Bisabolol, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Ceramide 2, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Glyceryl Behenate/Eicosadioate, Glyceryl Caprylate, Glyceryl Undecylenate, Guanycystamine HBr, Hexyl Laurate, Hydrated Silica, Hydrogen Dimethicone, Iron Oxides, Isododecane, Isopropyl Myristate, Laureth-7, Mica, Palmitoyl Hexapeptide-12, PEG-10 Phytosterol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Porphyra Umbilicalis Extract, Propylene Carbonate, Punica Granatum Extract, Silica, Sodium Chloride, Sodium Hyaluronate, Sodium Metabisulfite, Squalane, Stearalkonium Hectorite, Stearic Acid, Superoxide Dismutase, Tetrahexyldecyl Ascorbate, Titanium Dioxide, Tocopheryl Acetate, Tribehenin, Vitis Vinifera (Grape) Seed Extract, Vitis Vinifera (Grape) Seed Oil, Water

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.

Directions

- SHAKE WELL.
- 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 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.

Questions or comments

Call toll free 1-877-320-2381

PRINCIPAL DISPLAY PANEL - 18mL Tube with Applicator



SOLEIL
TOUJOURS®

with
Dr. Noëlle Sherber

PERPETUAL
RADIANCE™
BROAD SPECTRUM
SPF 20

COMPLEXION
PERFECTING FLUID

UNIVERSAL TINT

MINERAL BASED
SUNSCREEN

WATER RESISTANT
(80 MINUTES)

18 mL e 0.6 FL OZ

DRUG FACTS

Active Ingredients	Purpose
Titanium Dioxide (8%) Zinc Oxide (4.2%)	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.

Inactive Ingredients

Acrylates Copolymer, Aloe, Aloe Barbadosis Leaf Juice, Alumina, Aluminum Hydroxide, Argania Spinosa Kernel Oil, Ascorbyl Palmitate, Beeswax, Bisabolol, Butylhexyl Salicylate, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Ceraflin, Ceramide 2, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Glycerin, Glyceryl Behenate/Eicosanoate, Glyceryl Caprylate, Glyceryl Undecylenate, Guaranylcystamine HBr, Hexyl Laurate, Hydrated Silica, Hydrogen Dimethicone, Iron Oxides, Isododecane, Isopropyl Myristate, Laureth-7, Mica, Palmitoyl Hexapeptide-12, PEG-10 Phytosterol, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Porolithra Umbilicalis Extract, Propylene Carbonate, Punica Granatum Extract, Silica, Sodium Chloride, Sodium Hyaluronate, Sodium Metabisulfite, Squalane, Stearalkonium Hectorite, Stearic Acid, Superoxide Dismutase, Tetrahexyldecyl Ascorbate, Titanium Dioxide, Tocopherol Acetate, Tribenem, Vitis Vinifera (Grape) Seed Extract, Vitis Vinifera (Grape) Seed Oil, Water.

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.

Directions

- **SHAKE WELL.**
- 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 a 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.

Other Information

Protect this product from excessive heat and direct sun.

Questions or comments
Call 1-877-520-2381

DISTRIBUTED BY:

The Soleil Group, LLC
Bronxville, NY 10708
Obelisk sa, 1030 Brussels
www.soleiltojours.com
MADE IN U.S.A.



SOLEIL
Toujours®
with
Dr. Noëlle Sherber
PERPETUAL
RADIANCE™

BROAD SPECTRUM

SPF 20

COMPLEXION

PERFECTING FLUID

UNIVERSAL TINT

MINERAL BASED

SUNSCREEN

WATER RESISTANT

(80 MINUTES)

18 mL e 0.6 FL OZ

SOLEIL TOUJOURS PERPETUAL RADIANCE BROAD SPECTRUM SPF 20

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0185
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	17.6 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	41.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
12-HYDROXYSTEARIC ACID (UNII: 933ANU3H2S)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
STEARALKONIUM HECTORITE (UNII: O LX698AH5P)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERYL BEHENATE/EICOSADIOATE (UNII: 73CJJ317SR)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGAN OIL (UNII: 4V59G5UW9X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
LEVOMENOL (UNII: 24WE03BX2T)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
TRIBEHENIN (UNII: 8OC9U7TQZ0)	
CERAMIDE 2 (UNII: C04977SRJ5)	

.BETA.-SITOSTEROL (UNII: S347WMO6M4)
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)
CARAMEL (UNII: T9D99G2B1R)
CETYL DIMETHICONE 150 (UNII: 5L694Y0T22)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
GLYCERYL MONO UNDECYLENATE (UNII: IK8A76Q5G8)
GUANYLCYSTAMINE HYDROBROMIDE (UNII: PF69H864I0)
FERRIC OXIDE RED (UNII: 1K09F3G675)
ISODODECANE (UNII: A8289P68Y2)
LAURETH-7 (UNII: Z95S6G8201)
MICA (UNII: V8A1AW0880)
POLYGLYCERYL-4 ISO STEARATE (UNII: 820DPX33S7)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
SQUALANE (UNII: GW89575KF9)
ORGO TEIN (UNII: PKE82W49V1)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
SODIUM ALGINATE (UNII: C269C4G2ZQ)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
GRAPE SEED OIL (UNII: 930MLC8XGG)
VITIS VINIFERA SEED (UNII: C34U15ICXA)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)
PUNICA GRANATUM ROOT BARK (UNII: CLV24BT1D)
WATER (UNII: 059QF0KO0R)

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0185-2	18 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product	07/16/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	--	----------------------	--------------------

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0185) , pack(58443-0185) , manufacture(58443-0185) , analysis(58443-0185)

Revised: 1/2020

Prime Enterprises, Inc.