

SHISEIDO WHITE LUCENT DAY- avobenzone, octinoxate, and octocrylene emulsion
SHISEIDO AMERICAS CORPORATION

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.

SHISEIDO WHITE LUCENT DAY EMULSION

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Avobenzone 2.5%	Sunscreen
Octinoxate 7.4%	Sunscreen
Octocrylene 3.0%	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.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor
- **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

Inactive Ingredients

Water, SD Alcohol 40-B, Dimethicone, Dipropylene Glycol, Glycerin, Diisopropyl Sbeacate, Peg-60 Hydrogenated Castor Oil, Potassium Methoxysalicylate, Erythritol, Xanthan Gum, Tocopheryl Acetate, Peg/PPG-14/7 Dimethyl Ether, Peg/PPG-17/4 Dimethyl Ether, Dipotassium Glycyrrhizate, 2-O-Ethyl Ascorbic Acid, Caffeine, Ascorbyl Tetraisopalmitate, Phytosteryl Macadamiate, Angelica Keiskei Leaf/Stem Extract, Paeonia Albiflora Root Extract, Cratagus Monogyna Flower Extract, Rehmannia

Chinesis Root Extract, Ziziphu Jujuba Fruit Extract, Polyquaternium 51, PPG-17, Peg-240/HDI Copolymer BIS-Decyltetradeceth-20 Ether, Triethanolamine, Silica, Butylene Glycol, Isostearic Acid, PPG-3 Dipivalate, HDI/Trimethylol Hexyllactone Crosspolymer, Carbomer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, BHT, Sodium Metaphosphate, Alcohol, Tocopherol, Disodium EDTA, Sodium Metabisulfite, Prunus Yedoensis Leaf Extract, Phenoxyethanol, Benzoic Acid, Fragrance, Titanium Dioxide, Mica, Iron Oxides

Other information

Protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

SHISEIDO
GINZA TOKYO

White Lucent

Day Emulsion

BROAD SPECTRUM
SPF 23

SUNSCREEN

ReNeura Technology+™

50mL NET WT. 1.7 OZ.

White Lucent
Day Emulsion



Drug Facts (continued)

Directions

For sunscreen use:

■ apply liberally 15 minutes before sun exposure

■ use a water resistant sunscreen if swimming or sweating

■ reapply 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 ▶

Drug Facts (continued)

Inactive ingredients

WATER • SD ALCOHOL 40-B • DIMETHICONE •

DIPROPYLENE GLYCOL • GLYCERIN • OHSOPROPYL SEBACATE •

PEG-60 HYDROGENATED CASTOR OIL • POTASSIUMMETHOXY SALICYLATE •

ERYTHRITOL • XANTHAN GUM • TOCOPHERYL ACETATE •

PEG/PPG-14/7 DIMETHYL ETHER •

PEG/PPG-17/4 DIMETHYL ETHER •

DIPOTASSIUM GLYCERYLPHOSPHATE •

2-O-ETHYLASCORBIC ACID •

CAFFEINE •

ASCORBYL TETRAISOPALMITATE •

PHYTOSTERYL MACADAMATE •

ANGELICAE SIKESKE LEAF/STEM

EXTRACT •

PAEONIA ALBIFLORA ROOT EXTRACT •

CRATAEGUS MONOGYNIA ROOT EXTRACT •

REHMANNIA CHINENSIS ROOT

EXTRACT •

ZIZIPHUS JUJUBA FRUIT EXTRACT •

PHYLLA INCARNATA EXTRACT •

POTENTILLA RECTA ROOT EXTRACT •

POLYQUATERNIUM-51 • PPG-17 •

PEG-240/HDI COPOLYMER

BS-DECYL TETRADECETH-20 ETHER •

TRITHANOLAMINE • SILICA •

BUTYLENE GLYCOL •

ISOSTEARIC ACID •

PPG-3 DIPALATE •

HD/TRIMETHYLOL HEXYLACTONE

CROSSPOLYMER •

CARBOMER •

ACRYLATES/C10-30 ALKYL ACRYLATE

CROSSPOLYMER •

BHT • SODIUM METAPHOSPHATE •

ALCOHOL • TOCOPHEROL •

DISODIUM EDTA •

SODIUM METABISULFITE •

PRUNUS YEDDENSIS LEAF EXTRACT •

PHENOXYETHANOL • BENZOIC ACID •

FRAGRANCE • TITANIUM DIOXIDE •

MICA • IRON OXIDES •

SHISEIDO

GINZA TOKYO

White Lucent
Day Emulsion

BROAD SPECTRUM
SPF 23

SUNSCREEN

ReNeura Technology+™

Other Information

■ protect this product in this container from

See our website
for more information.

excessive heat
and direct sun.

**Questions or
Comments?**

Call toll free
1-800-906-7503

50mL NET WT. 1.7 OZ.

52x28.5x154

NS 1 2 3 4 5 6 7 8 9 0

SHISEIDO
WHITE LUCENT
DAY EMULSION
BROAD SPECTRUM
SPF 23

Reawaken your skin's sensors.
Illuminate your skin's radiance.

Focus on the neuroscience of your skin's senses. With this dewy smooth emulsion, ReNeura Technology+™ directs internal sensory signals, to make skin optimally responsive to the age-defying benefits of skincare. It protects skin against hazards throughout the day, as it brightens, diminishes the look of dark spots and unevenness, moisturizes, and smoothes lines. Illuminating you.

- Apply in the morning, after cleanser.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC.
DERMATOLOGIST-TESTED.

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen

Uses

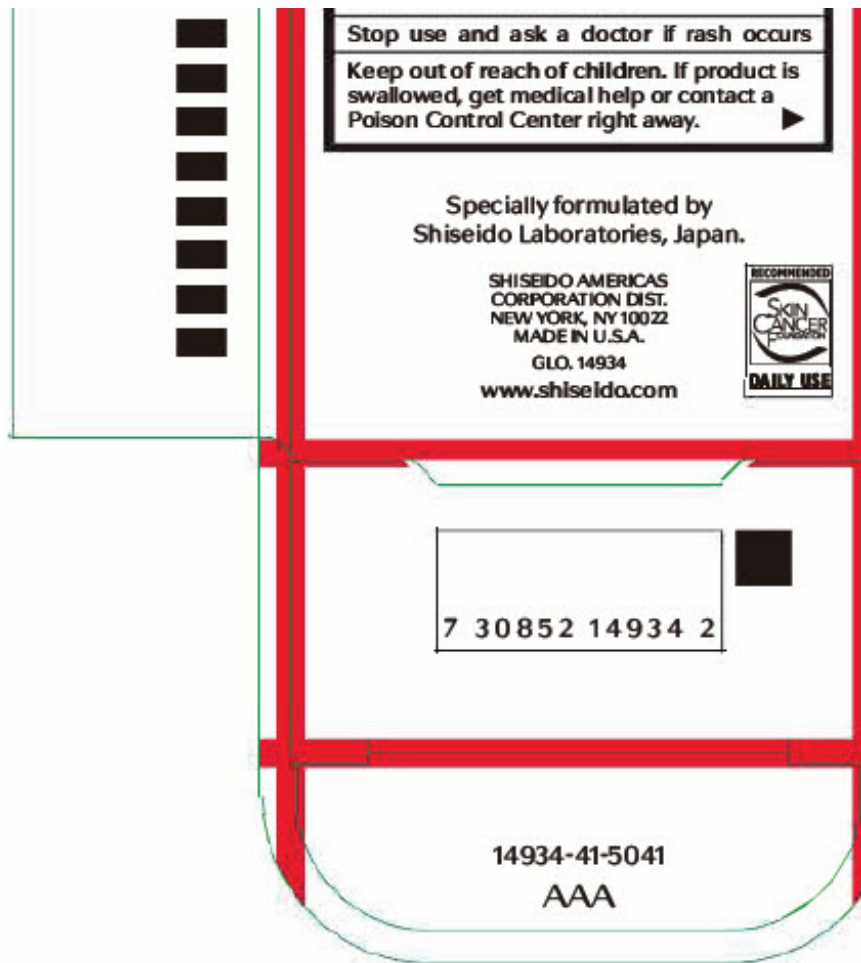
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Warnings

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.



SHISEIDO WHITE LUCENT DAY

avobenzone, octinoxate, and octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-463
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.285 g in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3.8036 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.542 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	

PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)
POTASSIUM METHOXYALICYLATE (UNII: 5G3H7U4Y7F)
ERYTHRITOL (UNII: RA96B954X6)
XANTHAN GUM (UNII: TTV12P4NEE)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)
CAFFEINE (UNII: 3G6A5W338E)
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)
ANGELICA KEISKEI TOP (UNII: AP628M4TQO)
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)
REHMANNIA GLUTINOSA ROOT (UNII: 1BEM3U6LQQ)
JUJUBE FRUIT (UNII: G55HNL2C70)
POTENTILLA ERECTA ROOT (UNII: B1896CKT6B)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
PPG-17 (UNII: OV0Q322E0U)
TROLAMINE (UNII: 9O3K93S3TK)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ISO STEARIC ACID (UNII: X33R8U0062)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5C0)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
ALCOHOL (UNII: 3K9958V90M)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
EDETATE DISODIUM (UNII: 7FLD91C86K)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
PRUNUS X YEDOENSIS LEAF (UNII: 1Z125GA907)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BENZOIC ACID (UNII: 8SKN0B0MIM)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-463-10	1 in 1 CARTON	01/01/2019	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2019	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICAS INC.		782677132	MANUFACTURE(58411-463) , ANALYSIS(58411-463)

Revised: 10/2019

SHISEIDO AMERICAS CORPORATION