

**SHISEIDO WHITE LUCENT ALL DAY BRIGHTENER N- avobenzone, octinoxate, octocrylene, and oxybenzone cream**  
**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.*

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**SHISEIDO WHITE LUCENT ALL DAY BRIGHTENER N**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
OXYBENZONE 1.0%	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**

- 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

**Inactive Ingredients**

WATER•SD ALCOHOL 40-B•DIMETHICONE•DIPROPYLENE GLYCOL•DIISOPROPYL SEBACATE•GLYCERIN•PEG-60 HYDROGENATED CASTOR OIL•POTASSIUM METHOXYSALICYLATE•XANTHAN GUM•PEG/PPG-14/7 DIMETHYL ETHER•TOCOPHERYL ACETATE•2-O-ETHYL ASCORBIC ACID•ASCORBYL TETRAISOPALMITATE•SODIUM HYALURONATE•PAEONIA SUFFRUTICOSA ROOT EXTRACT•CRATAEGUS MONOGYNA FLOWER EXTRACT•POLYQUATERNIUM-51•REHMANNIA CHINENSIS ROOT

EXTRACT•UNCARIA GAMBIR EXTRACT•HOULTTUYNIA CORDATA EXTRACT•PPG-17•PEG-240/HDI COPOLYMER BIS-DECYLTETRADECETH-20 ETHER•TRIETHANOLAMINE•SILICA•ISOSTEARIC ACID•BUTYLENE GLYCOL•CARBOMER•ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER•ALCOHOL•BHT•SODIUM METAPHOSPHATE•DISODIUM EDTA•TOCOPHEROL•ZINC OXIDE•SODIUM METABISULFITE•ALUMINA•PRUNUS YEDOENSIS LEAF EXTRACT•METHYLPARABEN•ETHYLPARABEN•PHENOXYETHANOL•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**

**SHI SEIDO**

WHITE LUCENT

All Day Brightener

BROAD SPECTRUM

SPF 23

SUNSCREEN

**PRO**APPROACH<sup>x2</sup>

50mL NET WT. 1.8 OZ.

52x28.5x1.54

1 2 3 4 5 6 7 8 9 0

SHISEIDO  
WHITE LUCENT  
ALL DAY BRIGHTENER N  
(DAY EMULSION)  
BROAD SPECTRUM  
SPF 23

Liberated from present and future concerns, skin achieves ideal radiance—and maintains it.

An advanced daytime brightening moisturizer that intensively evens out the skin tone and maintains a radiant look throughout every moment of the day, while protecting the skin against UV rays.

- Smooth over the face each morning after cleanser and softener.
- Avoid exposure to direct sunlight and high temperatures.
- Wipe the opening of the container and replace the cap firmly after use.
- Reducing the quantity you apply will lower the level of sun protection significantly.
- DERMATOLOGIST-TESTED

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Specially formulated by  
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS  
CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.  
GLO. 13484

7 30852 13484 3

13484-41-5040  
AAA

**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:  
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· wear long-sleeve shirts, pants, hats, and sunglasses  
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SHISEIDO

All Day Brightener N



WHITE LUCENT  
All Day Brightener  
BROAD SPECTRUM  
SPF 23  
SUNSCREEN

PROAPPROACH<sup>®</sup>2

50mL NET WT. 1.8 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

WATER - SD ALCOHOL 40-8 - DIMETHICONE - DIPROPYLENE GLYCOL - DIBENZOYL SEBACATE - GLYCERIN - PEG-20 HYDROGENATED CASTOR OIL - POTASSIUM METHOXYSAUCYLATE - XANTHAN GUM - PEG/PPG-14/7 DIMETHYL ETHER - TOCOPHERYL ACETATE - 2-(4-CETHYL ASCORBIC ACID - ASCORBYL TETRAISOPALMITATE - SODIUM HYALURONATE - PAEDONIS SUFFRUTICOSA ROOT EXTRACT - CRATAEGUS MONOGYNA FLOWER EXTRACT - POLYQUATERM-11(MAS) - REHMANIA CHINENSIS ROOT EXTRACT - UNCARIA GAMBIR EXTRACT - HOUTTUYNIA CORDATA EXTRACT - PPG-17 - PEG-240/HDI COPOLYMER - BIS-DECYL TETRADECETH-20 ETHER - TRIMETHANOLAMINE - SILICA - ISOSTEARIC ACID - BUTYLENE GLYCOL - CARBOMER - ACRYLATES/C10-30 ALKYL ACRYLATE COPOLYMER - ALCOHOL - BHT - SODIUM METAPHOSPHATE - CRODALIN EDTA - TOCOPHEROL - ZINC OXIDE - SODIUM METABISULFITE - ALUMINA - PRUNUS YEDDENSIS LEAF EXTRACT - METHYL PARABEN - ETHYL PARABEN - PHENOXYETHANOL - FRAGRANCE - TITANIUM DIOXIDE - MICA - IRON OXIDES

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**Questions or Comments?**

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# SHISEIDO WHITE LUCENT ALL DAY BRIGHTENER N

avobenzone, octinoxate, octocrylene, and oxybenzone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-295
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1283 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3796 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1539 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	513 mg in 50 mL

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
POTASSIUM METHOXYALICYLATE (UNII: 5G3H7U4Y7F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PAEONIA SUFFRUTICOSA ROOT (UNII: 7M7E9A2C8J)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
REHMANNIA GLUTINOSA ROOT (UNII: 1BEM3U6LQQ)	
HOULTTUYNIA CORDATA FLOWERING TOP (UNII: RH041UUZ22)	
PPG-17 (UNII: OV0Q322E0U)	
TROLAMINE (UNII: 9O3K93S3TK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISO STEARIC ACID (UNII: X33R8U0062)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	

ALUMINUM OXIDE (UNII: LMI26O6933)	
PRUNUS X YEDOENSIS LEAF (UNII: 1Z125GA907)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ETHYL PARABEN (UNII: 14255EXE39)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-295-60	1 in 1 CARTON	02/01/2017	
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 not final	part352	02/01/2017	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-295) , analysis(58411-295)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION