

**SHISEIDO ULTIMATE SUN PROTECTION- avobenzene, 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 ULTIMATE SUN PROTECTION LOTION**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 5.0%	Sunscreen
OXYBENZONE 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
- 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

**Inactive Ingredients**

WATER·DIMETHICONE·SD ALCOHOL 40-B·TALC·METHYL METHACRYLATE

CROSSPOLYMER·ISODODECANE·CETYL ETHYLHEXANOATE·DIISOPROPYL  
SEBACATE·TRIETHYLHEXANOIN·LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL  
DIMETHICONE·GLYCERIN·DEXTRIN PALMITATE·SUCROSE TETRASTEARATE  
TRIACETATE·POLYBUTYLENE GLYCOL/PPG-9/1  
COPOLYMER·TRIMETHYLSILOXYSILICATE·XYLITOL·SILICA·SODIUM  
CHLORIDE·PEG/PPG-14/7 DIMETHYL ETHER·SAXIFRAGA SARMENTOSA  
EXTRACT·SOPHORA ANGUSTIFOLIA ROOT EXTRACT·DISTEARDIMONIUM  
HECTORITE·ISOSTEARIC ACID·CALCIUM STEARATE·TRISODIUM EDTA·VINYL  
DIMETHICONE/METHICONE SILSESQUOXANE  
CROSSPOLYMER·ALCOHOL·BHT·BUTYLENE GLYCOL·STEARIC ACID·SODIUM  
METABISULFITE·SYZYGIUM JAMBOS LEAF EXTRACT·TOCOPHEROL·POLYSILICONE-  
2·METHYLPARABEN·FRAGRANCE·IRON OXIDES·

**Other information**

- protect this product in this container from excessive heat and direct sun.
- avoid contact with clothing and other textiles-may stain.

**Questions or comments?**

Call toll free 1-800-906-7503

**PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton**

**SHISEIDO**  
**GINZA TOKYO**

Ultimate  
Sun Protection Lotion

**50+**

**WetForce**  
**Turns Invisible**

BROAD SPECTRUM  
SPF 50+

For Face/Body

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

50mL 1.6 FL. OZ.

Ultimate Sun Protection Lotion



BROAD SPECTRUM SPF 50+

SHISEIDO  
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BROAD SPECTRUM  
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For Face/Body

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(80 MINUTES)

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50mL 1.6 FL. OZ.

### Drug Facts (continued)

#### Directions

- children under 6 months:  
Ask a doctor

#### Inactive ingredients

WATER • DIMETHICONE • SD ALCOHOL 40-B • TALC •  
METHYL METHACRYLATE CROSSPOLYMER •  
ISODODECANE • CETYL ETHYLHEXANOATE •  
DIISOPROPYL SEBACATE • TRIETHYLHEXANDIN •  
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL  
DIMETHICONE •  
GLYCERIN • DEXTRIN PALMITATE •  
SUCROSE TETRASTEARATE TRIACETATE •  
POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER •  
TRIMETHYLSILOXYSILICATE • XYLITOL • SILICA •  
SODIUM CHLORIDE •  
PEG/PPG-14/7 DIMETHYL ETHER •  
SAXIFRAGA SARMENTOSA EXTRACT •  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •  
DISTEARDIMONIUM HECTORITE •  
ISOSTEARIC ACID • CALCIUM STEARATE •  
TRISODIUM EDTA •  
VINYL DIMETHICONE/METHICONE SILSESQUOXANE  
CROSSPOLYMER •  
ALCOHOL • BHT • BUTYLENE GLYCOL •  
STEARIC ACID • SODIUM METABISULFITE •  
SYZYGIUM JAMBOS LEAF EXTRACT • TOCOPHEROL •  
POLYSILICONE-2 • METHYLPARABEN • FRAGRANCE •  
IRON OXIDES •

#### Other Information

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from excessive heat and direct sun.
- avoid contact with clothing and  
other textiles-may stain. ▼

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Questions or Comments? Call toll free 1-800-906-7503

Drug Facts (continued)

14227-41-2540  
AAA

SHISEIDO  
ULTIMATE SUN PROTECTION LOTION  
BROAD SPECTRUM SPF 50+

Powerful sun protection featuring WetForce technology. Its protective veil becomes stronger as it comes into contact with water or perspiration,\* so you can keep enjoying being active outdoors. The smooth texture feels comfortable, and the lotion turns invisible on any skin tone.

\*To activate WetForce technology, expose the applied area to water for 15 minutes or perspiration for 30 minutes.

•Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC.  
DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.

Drug Facts

Active ingredients	Purpose
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OXYBENZONE 3.0% .....	Sunscreen

Uses

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Warnings

For external use only

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When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs ▶

Drug Facts (continued)

Warnings

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

For sunscreen use: ■ 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 ▶

Specially formulated by  
Shiseido Laboratories, Japan.  
SHISEIDO AMERICAS CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.  
G.L.O. 14227  
www.shiseido.com



<http://s1872.com/14227AA>  
See our website  
for more information.

## SHISEIDO ULTIMATE SUN PROTECTION

avobenzone, octinoxate, octocrylene, and oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-359
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1288 mg in 50 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2524 mg in 50 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2575 mg in 50 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1545 mg in 50 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)	

SUCROSE TETRASTEARATE TRIACETATE (UNII: 1K7LBQ045N)
TRIMETHYLSILOXY SILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
XYLITOL (UNII: VCQ006KQ1E)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
ISOSTEARIC ACID (UNII: X33R8U0062)
CALCIUM STEARATE (UNII: 776XM7047L)
EDETATE TRISODIUM (UNII: 420IP921MB)
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
ALCOHOL (UNII: 3K9958V90M)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
STEARIC ACID (UNII: 4ELV7Z65AP)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
METHYL PARABEN (UNII: A2I8C7HI9T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-359-10	1 in 1 CARTON	02/01/2018	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:58411-359-11	1 in 1 CARTON	02/01/2018	
2		100 mL in 1 BOTTLE, PLASTIC; 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	02/01/2018	

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

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-359) , analysis(58411-359)

