

**SHISEIDO ULTIMATE SUN PROTECTOR- octisalate, homosalate, octocrylene, and avobenzone lotion**

**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 PROTECTOR LOTION**

***Drug Facts***

| <b><i>Active ingredients</i></b> | <b><i>Purpose</i></b> |
|----------------------------------|-----------------------|
| Octisalate 5.0%                  | Sunscreen             |
| Avobenzone 2.3%                  | Sunscreen             |
| Homosalate 10.0%                 | Sunscreen             |
| Octocrylene 5.0%                 | 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.

**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 two 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▪DIISOPROPYL SEBACATE▪TALC▪METHYL METHACRYLATE  
CROSSPOLYMER▪DIMETHICONE▪PEG/PPG-9/2 DIMETHYL ETHER▪SD ALCOHOL 40-  
B▪LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL  
DIMETHICONE▪TRIETHYLHEXANOIN▪GLYCERIN▪DEXTRIN PALMITATE▪SUCROSE  
TETRASTEARATE TRIACETATE▪ISODODECANE▪PPG-3  
DIPIVALATE▪TRIMETHYLSILOXYSILICATE▪SILICA▪SODIUM CHLORIDE▪PEG/PPG-14/7  
DIMETHYL ETHER▪SAXIFRAGA SARMENTOSA EXTRACT▪CAMELLIA SINENSIS LEAF  
EXTRACT▪SOPHORA ANGUSTIFOLIA ROOT EXTRACT▪PPG-17▪DISTEARDIMONIUM  
HECTORITE▪CALCIUM STEARATE▪ISOSTEARIC ACID▪PALMITIC ACID▪TRISODIUM  
EDTA▪ALCOHOL▪SILICA DIMETHYL SILYLATE▪VINYL DIMETHICONE/METHICONE  
SILSESQUIOXANE CROSSPOLYMER▪PEG-6▪BHT▪TOCOPHEROL▪BUTYLENE  
GLYCOL▪STEARIC ACID▪SODIUM METABISULFITE▪SYZYGIUM JAMBOS LEAF  
EXTRACT▪POLYSILICONE-2▪METHYL PARABEN▪FRAGRANCE▪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 - 150 mL Bottle Label**

SHISEIDO  
GINZA TOKYO

Ultimate  
Sun Protector Lotion

50+

SynchroShield  
WetForce x HeatForce

Turns Invisible

BROAD SPECTRUM  
SPF 50+

For Face/Body

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

150mL 5 FL. OZ.

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WATER RESISTANT  
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150mL 5 FL. OZ.



SHISEIDO  
ULTIMATE SUN PROTECTOR LOTION  
BROAD SPECTRUM SPF 50+

Powerful sun protection with SynchroShield™. The protective veil becomes even stronger whenever it senses heat, water or perspiration\*. This lotion provides a seamless protection against UVA/UVB rays, urban pollutants\*\* and dryness. Blends in rapidly. Enriched with skincare ingredients to help prevent the appearance of fine lines, wrinkles and uneven skin tone.

•Featuring HeatForce & WetForce technology. With heat, water or perspiration, additional strength within the protective veil is activated.\*

NON-COMEDOGENIC. DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.

\*The HeatForce technology is activated on hot days, after the formula is applied to the skin. To activate the WetForce technology, expose the applied area to water or perspiration for 30 minutes. \*\*dust and soot

**Drug Facts**

**Active ingredients**

| Active ingredients | Purpose   |
|--------------------|-----------|
| AVOBENZONE 2.3%    | Sunscreen |
| HOMOSALATE 10.0%   | Sunscreen |
| OCTISALATE 5.0%    | Sunscreen |
| OCTOCRYLENE 5.0%   | 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**

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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 ■children under 6 months: Ask a doctor

**Inactive ingredients** WATER · DIISOPROPYL SEBACATE · TALC · METHYL METHACRYLATE COPOLYMER · DIMETHICONE · PEG/PPG-9/2 DIMETHYL ETHER · SD ALCOHOL 40-B · LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · TRIETHYLHEXANOIN · GLYCERIN · DEXTRIN PALMITATE · SUCROSE TETRASTEARATE TRIACETATE · ISODODECANE · PPG-3 DIPIVALATE · TRIMETHYLSILOXYMETHYL DIMETHICONE · SILICA · SODIUM CHLORIDE · PEG/PPG-14/7 DIMETHYL ETHER · SAXIFRAGA SARMENTOSA EXTRACT · CAMELLIA SINENSIS LEAF EXTRACT · SOPHORA ANGUSTIFOLIA ROOT EXTRACT · PPG-17 · DISTEARDIMONIUM HECTORITE · CALCIUM STEARATE · ISOSTEARIC ACID · PALMITIC ACID · TRISODIUM EDTA · ALCOHOL · SILICA DIMETHYL Silylate · VINYL DIMETHICONE/METHICONE SILSESQUOXANE COPOLYMER · PEG-6 · BHT · TOCOPHEROL · BUTYLENE GLYCOL · STEARIC ACID · SODIUM METABISULFATE · SYZYGIUM JAMBOS LEAF EXTRACT · POLYSILOXANE-2 · METHYLPARABEN · FRAGRANCE · 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

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





## SHISEIDO ULTIMATE SUN PROTECTOR

octisalate, homosalate, octocrylene, and avobenzone lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58411-481 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength       |
|---|-------------------|----------------|
| <b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)   | OCTISALATE        | 50 mg in 1 mL  |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)       | HOMOSALATE        | 100 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM) | OCTOCRYLENE       | 50 mg in 1 mL  |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)       | AVOBENZONE        | 23 mg in 1 mL  |

### Inactive Ingredients

| Ingredient Name  | Strength |
|--|----------|
| <b>WATER</b> (UNII: 059QF0K00R)  |          |
| <b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)                                   |          |
| <b>TALC</b> (UNII: 7SEV7J4R1U)   |          |
| <b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EG97988M5Q) |          |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |          |
| <b>PEG/PPG-9/2 DIMETHYL ETHER</b> (UNII: LM6Q66468X)                             |          |
| <b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)       |          |
| <b>TRIETHYLHEXANO IN</b> (UNII: 7K3W1BIU6K)                                      |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |          |
| <b>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)                     |          |
| <b>SUCROSE TETRASTEARATE TRIACETATE</b> (UNII: 1K7LBQ045N)                       |          |
| <b>ISODODECANE</b> (UNII: A8289P68Y2)  |          |
| <b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)                  |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)  |          |
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  |          |
| <b>PEG/PPG-14/7 DIMETHYL ETHER</b> (UNII: 6DNW9T7YT2)                            |          |
| <b>SAXIFRAGA STOLONIFERA LEAF</b> (UNII: O3TMV4903H)                             |          |

|   |
|---|
| GREEN TEA LEAF (UNII: W2ZU1RY8B0)   |
| SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)                                |
| PPG-17 (UNII: OV0Q322E0U)   |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)                              |
| CALCIUM STEARATE (UNII: 776XM7047L)                                       |
| ISOSTEARIC ACID (UNII: X33R8U0062)  |
| PALMITIC ACID (UNII: 2V16EO95H1)  |
| EDETATE TRISODIUM (UNII: 420IP921MB)                                      |
| ALCOHOL (UNII: 3K9958V90M)  |
| SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)                               |
| VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR) |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)                                |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)                               |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)                                     |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)  |
| STEARIC ACID (UNII: 4ELV7Z65AP)   |
| SODIUM METABISULFITE (UNII: 4VON5FNS3C)                                   |
| SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)                                   |
| METHYLPARABEN (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:58411-48-1-10 | 1 in 1 CARTON   | 01/01/2020           |                    |
| 1 |                   | 150 mL in 1 BOTTLE; Type 0: Not a Combination Product |                      |                    |
| 2 | NDC:58411-48-1-11 | 1 in 1 CARTON   | 01/01/2020           |                    |
| 2 |                   | 50 mL in 1 BOTTLE; 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                                  | 01/01/2020           |                    |

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

### Establishment

| Name                   | Address | ID/FEI    | Business Operations                          |
|------------------------|---------|-----------|--|
| SHISEIDO AMERICAS INC. |         | 782677132 | MANUFACTURE(58411-481) , ANALYSIS(58411-481) |