

**SHISEIDO ULTIMATE SUN PROTECTOR- octisalate, octocrylene, zinc oxide cream**

**Shiseido Americas Corporation**

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**SHISEIDO ULTIMATE SUN PROTECTOR**

**Drug Facts**

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**Active ingredients**

Octisalate 3.0%  
Octocrylene 3.0%  
Zinc Oxide 19.4%

**Purpose**

Sunscreen

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**Uses**

- helps prevent sunburn

**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**

- 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. - 2p.m.
- wear long-sleeve shirts, pant, hats, and sunglasses
- children under 6 months: Ask a doctor

WATER □ DIISOPROPYL SEBACATE □ ISOPROPYL MYRISTATE □ ALCOHOL DENAT. □ PEG/PPG-9/2 DIMETHYL ETHER □ GLYCERIN □ ALCOHOL □ PPG-3 DIPIVALATE □ TALC □ POLYGLYCERYL-6 POLYRICINOLEATE □ SILICA □ DEXTRIN PALMITATE □ DEXTRIN

PALMITATE/ETHYLHEXANOATE□ACRYLAMIDES/DMAPA ACRYLATES/METHOXY PEG  
METHACRYLATE COPOLYMER□DIPOTASSIUM GLYCYRRHIZATE□AMINOETHANESULFINIC  
ACID□PEG/PPG-14/7 DIMETHYL ETHER□SAXIFRAGA SARMENTOSA EXTRACT□CAMELLIA  
SINENSIS LEAF EXTRACT□EUCHEUMA SERRA/GRATELOUPIA SPARSA/SACCHARINA  
ANGUSTATA/ULVA LINZA/UNDARIA PINNATIFIDA EXTRACT□SODIUM HYALURONATE□  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT□SACCHARINA ANGUSTATA/UNDARIA  
PINNATIFIDA EXTRACT□HYDROGEN DIMETHICONE□DIMETHYLACRYLAMIDE/SODIUM  
ACRYLOYLDIMETHYLAURATE CROSSPOLYMER□HYDROXYPROPYL METHYLCELLULOSE  
STEAROXY ETHER□SUCCINOGLYCAN□TOCOPHEROL□BHT□BUTYLENE GLYCOL□STEARIC  
ACID□SODIUM METABISULFITE□PEG-6□BIS-BUTYLDIMETHICONE POLYGLYCERYL-3□  
SYZYGIUM JAMBOS LEAF EXTRACT□CHLORPHENESIN□FRAGRANCE

***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- 50mL Tube**

SHISEIDO

GINZA TOKYO

Ultimate Sun Protector Cream

SPF 50

Advanced Protection & Age Defense

BROAD SPECTRUM SPF 50

WATER RESISTANT (80 MINUTES)

SUNSCREEN

SHISEIDO  
ULTIMATE SUN PROTECTOR CREAM  
BROAD SPECTRUM SPF 50

A smooth, breathable sunscreen cream that provides powerful protection with SynchroShieldRepair™. Protects seamlessly against UVA/UVB and micro dust. The protective veil becomes more even and strengthened with heat and water\*, and it re-smoothes the surface on its own. Formulated with Algae complex and Hyaluronic Acid. Visibly improves the look of fine lines, and the loss of plumpness and smoothness in 4 weeks.\*\* Enjoy every single moment of your active life.

\*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.  
\*\*clinically tested on 33 people

NO-OXYBENZONE • NO-OCTINOXATE • NO-PARABENS  
NON-COMEDOGENIC • DERMATOLOGIST AND  
OPHTHALMOLOGIST-TESTED

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Specially formulated by  
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS  
CORPORATION DIST.  
NEW YORK, NY 10017  
MADE IN U.S.A.  
GLO. 22472  
www.shiseido.com



**Drug Facts**  
(continued)

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**SynchroShieldRepair™**  
SynchroShieldRepair™, our exclusive technology for a strong protective veil.



30% plant-derived plastic\*\*\* tube.  
\*\*\*Without cap

http://s1872.com/22472AA  
See our website for more information.



SHISEIDO  
GINZA TOKYO

Ultimate Sun Protector  
Cream

SPF  
50

Advanced Protection & Age Defense

BROAD SPECTRUM SPF 50  
WATER RESISTANT (80 MINUTES)  
SUNSCREEN

50mL NET WT. 2.1 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

Water • Disopropyl Sebacate • Isopropyl Myristate • Alcohol Denat. • PEG/PPG-9/2 Dimethyl Ether • Glycerin • Alcohol • PPG-3 Dipalate • Talc • Polyglyceryl-6 Polyricinoleate • Silica • Dextrin Palmitate • Dextrin Palmitate/Ethylhexanoate • Acrylamides/DMAEA • Acrylates/Methoxy PEG • Methacrylate Copolymer • Dipotassium Glycylthiazate • Aminoethanesulfonic Acid • PEG/PPG-14/7 Dimethyl Ether • Sawiraga Sarmientosa Extract • Camellia Sinensis Leaf Extract • Eucyema Serra/Grateloupia Sparsa/Saccharina Angustata/Ulva Linza/Undaria Pinnatifida Extract • Sodium Hyaluronate • Sophora Angustifolia Root Extract • Saccharina Angustata/Undaria Pinnatifida Extract • Hydrogen Dimethicone • Dimethylacrylamide/Sodium Acryloyldimethyltaurate Crosspolymer • Hydroxypropyl Methylcellulose Stearate Ether • Succinoglycan • Tocopherol • BHT • Butylene Glycol • Stearic Acid • Sodium Metabisulfite • PEG-6 • Bis-Butyl Dimethicone Polyglyceryl-3 • Syzygium Jamboos Leaf Extract • Chlorphenesin • Fragrance

**Other Information**

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**Questions or Comments?**

Call toll free  
1-800-906-7503

<M129/26-81>

**SHISEIDO ULTIMATE SUN PROTECTOR**

octisalate, octocrylene, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-971
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1.8105 g in 50 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (ETHYLHEXYL SALICYLATE - UNII:4X49Y0596W)	OCTISALATE	1.8105 g in 50 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	11.7079 g in 50 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)
<b>ALCOHOL</b> (UNII: 3K9958V90M)
<b>PEG/PPG-9/2 DIMETHYL ETHER</b> (UNII: LM6Q66468X)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>TALC</b> (UNII: 7SEV7J4R1U)
<b>POLYGLYCERYL-6 POLYRICINOLEATE</b> (UNII: YPM0ZOC2HR)
<b>SILICA</b> (UNII: ETJ7Z6XBU4)
<b>DEXTRIN PALMITATE (CORN; 20000 MW)</b> (UNII: 89B2BSF9I3)
<b>DIPOTASSIUM GLYCYRRHIZATE</b> (UNII: CA2Y0FE3FX)
<b>AMINOETHANESULFINIC ACID</b> (UNII: 5L08GE4332)
<b>PEG/PPG-14/7 DIMETHYL ETHER</b> (UNII: 6DNW9T7YT2)
<b>SAXIFRAGA STOLONIFERA LEAF</b> (UNII: O3TMV4903H)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>SODIUM HYALURONATE</b> (UNII: YSE9PPT4TH)
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K)
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)
<b>HYPROMELLOSE 2208 0.45% STEAROXY ETHER</b> (UNII: MG58AH4FJ8)
<b>SUCCINOGLYCAN (AGROBACTERIUM TUMEFACIENS)</b> (UNII: YP632MQS35)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>BHT</b> (UNII: 1P9D0Z171K)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-971-60	1 in 1 BOX	03/01/2025	
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 Drug	M020	03/01/2025	

**Labeler** - Shiseido Americas Corporation (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
Shiseido America Inc.		782677132	manufacture(58411-971) , analysis(58411-971)

