

SHISEIDO ULTIMATE SUN PROTECTION- octinoxate, octocrylene, titanium dioxide, and zinc oxide 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.

SHISEIDO ULTIMATE SUN PROTECTION

Drug Facts

| <i>Active ingredients</i> | <i>Purpose</i> |
|----------------------------------|-----------------------|
| OCTINOXATE 7.4% | Sunscreen |
| OCTOCRYLENE 3.0% | Sunscreen |
| TITANIUM DIOXIDE 1.4% | Sunscreen |
| ZINC OXIDE 16.4% | 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, 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•DIMETHICONE•SD ALCOHOL 40-B•ISOHEXADECANE•BUTYLENE
GLYCOL•ISOPROPYL MYRISTATE•METHYL METHACRYLATE CROSSPOLYMER•LAURYL
PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE•XYLITOL•GLYCERIN•POLYBUTYLENE GLYCOL/PPG-9/1
COPOLYMER•ISODODECANE•TRIMETHYLSILOXYSILICATE•DISTEARDIMONIUM
HECTORITE•PEG-6•DEXTRIN PALMITATE•PEG-32•PEG/PPG-14/7 DIMETHYL
ETHER•SAXIFRAGA SARMENTOSA EXTRACT•SCUTELLARIA BAICALENSIS ROOT
EXTRACT•ONONIS SPINOSA ROOT EXTRACT•ECTOIN•SOPHORA ANGUSTIFOLIA ROOT
EXTRACT•SILICA•HYDROGEN DIMETHICONE•CARBOXYDECYL
TRISILOXANE•ALUMINUM HYDROXIDE•STEARIC ACID•TRISODIUM
EDTA•POLYMETHYLSILSESQUIOXANE•TALC•ALCOHOL•BHT•SYZYGIUM JAMBOS LEAF
EXTRACT•TOCOPHEROL•PHENOXYETHANOL•FRAGRANCE•

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 Tube Carton

SHISEIDO

GINZA TOKYO

Ultimate

Sun Protection Cream

50+

WetForce

BROAD SPECTRUM

SPF 50+

For Face

WATER RESISTANT

(80 MINUTES)

SUNSCREEN

50mL NET WT. 2 OZ.

Ultimate Sun Protection Cream



BROAD SPECTRUM SPF 50+

SHISEIDO
GINZA TOKYO

Ultimate
Sun Protection Cream

50+
WetForce

BROAD SPECTRUM
SPF 50+

For Face

WATER RESISTANT
(80 MINUTES)

SUNSCREEN

Drug Facts (continued)

Directions

- children under 6 months:
Ask a doctor

Inactive ingredients

WATER • DIMETHICONE • SD ALCOHOL 40-B •
ISOHEXADECANE • BUTYLENE GLYCOL •
ISOPROPYL MYRISTATE •
METHYL METHACRYLATE COPOLYMER •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
XYLITOL • GLYCERIN •
POLYBUTYLENE GLYCOL/PPG-9/1
COPOLYMER •
ISODODECANE • TRIMETHYLSILOXYSILICATE •
DISTEARDIMONIUM HECTORITE • PEG-6 •
DEXTRIN PALMITATE • PEG-32 •
PEG/PPG-14/7 DIMETHYL ETHER •
SAXIFRAGA SARMENTOSA EXTRACT •
SCUTELLARIA BAICALENSIS ROOT EXTRACT •
ONONIS SPINOSA ROOT EXTRACT • ECTOIN •
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •
SILICA • HYDROGEN DIMETHICONE •
CARBOXYDECYL TRISILOXANE •
ALUMINUM HYDROXIDE • STEARIC ACID •
TRISODIUM EDTA •
POLYMETHYLSILSESQUOXANE • TALC •
ALCOHOL • BHT •
SYZYGIUM JAMBOS LEAF EXTRACT •
TOCOPHEROL • PHENOXYETHANOL •
FRAGRANCE •

Other Information

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

50mL NET WT. 2 OZ.

Avoid contact with clothing and other textiles-may stain.

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

SHISEIDO
ULTIMATE SUN PROTECTION CREAM
BROAD SPECTRUM SPF 50+
FOR FACE

Providing powerful protection for your skin, this innovative protective veil actually becomes even more effective on the applied area when exposed to water for 15 minutes*, because of its WetForce technology. This unique formula includes beneficial ingredients to help prevent skin dryness. Ideal for outdoor activities and sports, it provides high sun protection, yet is comfortable and gentle on the skin.

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

- Be sure to reapply immediately after towel-drying skin.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC.
DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.

Drug Facts

Drug Facts
(continued)

Warnings

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Flammable. Do not use near heat, 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

56x34.5x114.5 123

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| Active ingredients | Purpose |
|-----------------------------|-----------|
| OCTINOXATE 7.4% | Sunscreen |
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| TITANIUM DIOXIDE 1.4% | Sunscreen |
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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 ▶

Specially formulated by
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 14471
www.shiseido.com



- 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 ▶

<http://s1872.com/14471AA>
See our website
for more information.

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14471-41-5040
AAA

SHISEIDO ULTIMATE SUN PROTECTION

octinoxate, octocrylene, titanium dioxide, and zinc oxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58411-254 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 4255 mg in 50 mL |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 1725 mg in 50 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 805 mg in 50 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 9430 mg in 50 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| ISOHEXADECANE (UNII: 918X1OUF1E) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA) | |
| XYLITOL (UNII: VCQ006KQ1E) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ISODODECANE (UNII: A8289P68Y2) | |
| TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN) | |
| DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L) | |
| POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ) | |
| POLYETHYLENE GLYCOL 1600 (UNII: 1212Z7S33A) | |
| PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2) | |
| SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H) | |
| SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S) | |
| ONONIS SPINOSA ROOT (UNII: FD2FMC53M1) | |
| ECTOINE (UNII: 7GXZ3858RY) | |
| SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| EDETATE TRISODIUM (UNII: 420IP921MB) | |
| POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69) | |
| TALC (UNII: 7SEV7J4R1U) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF) | |
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58411-254-60 | 1 in 1 CARTON | 02/01/2015 | |
| 1 | | 50 mL in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:58411-254-61 | 1 in 1 CARTON | 02/01/2015 | |
| 2 | | 30 mL in 1 TUBE; Type 0: Not a Combination Product | | |

| | | | | |
|---|------------------|--|------------|------------|
| 3 | NDC:58411-254-62 | 1 in 1 CARTON | 02/01/2015 | |
| 3 | | 15 mL in 1 TUBE; Type 0: Not a Combination Product | | |
| 4 | NDC:58411-254-80 | 2 mL in 1 POUCH; Type 0: Not a Combination Product | 02/01/2015 | 12/31/2019 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 02/01/2015 | |

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|--|
| SHISEIDO AMERICA INC. | | 782677132 | manufacture(58411-254) , analysis(58411-254) |

Revised: 6/2020

SHISEIDO AMERICAS CORPORATION