

SHISEIDO ULTIMATE SUN PROTECTOR- octisalate, titanium dioxide, octocrylene, 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 PROTECTOR CREAM

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Octisalate 5.0%	Sunscreen
Octocrylene 7.0%	Sunscreen
Titanium Dioxide 3.8%	Sunscreen
Zinc Oxide 19.4%	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, 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•DIMETHICONE•SD ALCOHOL 40-B•ISOPROPYL MYRISTATE•PEG/PPG-9/2
DIMETHYL ETHER•METHYL METHACRYLATE CROSSPOLYMER•LAURYL PEG-9
POLYDIMETHYLSILOXYETHYL
DIMETHICONE•GLYCERIN•ISOHEXADECANE•POLYBUTYLENE GLYCOL/PPG-9/1
COPOLYMER•ISODODECANE•TRIMETHYLSILOXYSILICATE•DISTEARDIMONIUM
HECTORITE•DEXTRIN PALMITATE•PEG/PPG-14/7 DIMETHYL ETHER•SAXIFRAGA
SARMENTOSA EXTRACT•SCUTELLARIA BAICALENSIS ROOT EXTRACT•CAMELLIA
SINENSIS LEAF EXTRACT•ONONIS SPINOSA ROOT EXTRACT•SODIUM
HYALURONATE•SOPHORA ANGUSTIFOLIA ROOT EXTRACT•ALUMINUM
HYDROXIDE•SILICA•HYDROGEN DIMETHICONE•STEARIC ACID•SORBITAN
SESQUIISOSTEARATE•CARBOXYDECYL TRISILOXANE•TRISODIUM EDTA•BUTYLENE
GLYCOL•ALCOHOL•POLYMETHYLSILSESQUIOXANE•TALC•TOCOPHEROL•BHT•SODIUM
METABISULFITE•PEG-6•SYZYGIUM JAMBOS LEAF
EXTRACT•PHENOXYETHANOL•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 - 50 mL Tube Label

SHISEIDO

GINZA TOKYO

Ultimate

Sun Protector Cream

50+

SynchroShield

WetForce × HeatForce

BROAD SPECTRUM

SPF 50+

For Face

WATER RESISTANT

(80 MINUTES)

SUNSCREEN

50mL NET WT. 2 OZ.

SHISEIDO
GINZA TOKYO

Ultimate
Sun Protector Cream

50+



SynchroShield
WetForce x HeatForce

BROAD SPECTRUM
SPF 50+
For Face
WATER RESISTANT

(80 MINUTES)

SUNSCREEN

50mL NET WT. 2 OZ.



SHISEIDO
ULTIMATE SUN PROTECTOR CREAM
BROAD SPECTRUM SPF 50+

Powerful sun protection with SynchroShield™. The protective veil becomes even stronger whenever it senses heat, water or perspiration*. Enriched with skincare ingredients to help prevent the appearance of fine lines, wrinkles and uneven skin tone.

*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.

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Flammable : Do not use near heat, flame, or while smoking.

Directions ■ apply liberally 15 minutes before sun exposure ■ reapply:
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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 · ISOPROPYL MYRISTATE ·
PEG/PPG-9/2 DIMETHYL ETHER · METHYL METHACRYLATE CROSSPOLYMER · LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE · GLYCERIN ·
ISOHEXADECANE · POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER · ISODODECANE · TRIMETHYLSILOXYSILICATE · DISTEARDIMONIUM HECTORITE ·
DEXTRIN PALMITATE · PEG/PPG-14/7 DIMETHYL ETHER · SAXIFRAGA SARMENTOSA EXTRACT · SCUTELLARIA BAICALENSIS ROOT EXTRACT ·
CAMELLIA SINENSIS LEAF EXTRACT · ONONIS SPINOSA ROOT EXTRACT · SODIUM HYALURONATE · SOPHORA ANGUSTIFOLIA ROOT EXTRACT ·
ALUMINUM HYDROXIDE · SILICA · HYDROGEN DIMETHICONE · STEARIC ACID · SORBITAN SESQUISEOSTEARATE · CARBOXYDECYL TRISILOXANE ·
TRISODIUM EDTA · BUTYLENE GLYCOL · ALCOHOL · POLYMETHYLSILSESQUOXANE · TALC · TOCOPHEROL · BHT · SODIUM METABISULFITE · PEG-6 ·
SYZYGIUM JAMBOS LEAF EXTRACT · PHENOXYETHANOL · 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

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



Blue Conscious Project

Specially formulated by
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.

GLO. 15676

www.shiseido.com

<http://s1872.com/15676AA>

See our website for more
information.



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SHISEIDO ULTIMATE SUN PROTECTOR

octisalate, titanium dioxide, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-480
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	3.105 g in 50 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	2.359 g in 50 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	4.347 g in 50 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12.047 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG/PPG-9/2 DIMETHYL ETHER (UNII: LM6Q66468X)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: 657L0NC5MT)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X10UF1E)	
ISODODECANE (UNII: A8289P68Y2)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SORBITAN SESQUISOESTEARATE (UNII: VU97D01BF9)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
TALC (UNII: 7SEV7J4R1U)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
.ALPHA.-CELLULOSE (UNII: B55QGZ19A)	
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:58411-480-60	1 in 1 CARTON	01/01/2020	
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 FINAL	part352	01/01/2020	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment			
Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICAS INC.		782677132	MANUFACTURE(58411-480) , ANALYSIS(58411-480)

Revised: 10/2019

SHISEIDO AMERICAS CORPORATION