

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

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.

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•BUTYLENE GLYCOL•ISOPROPYL

MYRISTATE•ISOHEXADECANE•SD ALCOHOL 40-B•ISODODECANE•METHYL
METHACRYLATE CROSSPOLYMER•PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE•TRIMETHYLSILOXYSILICATE•POLYBUTYLENE GLYCOL/PPG-9/1
COPOLYMER•XYLITOL•GLYCERIN•METHYL GLUCETH-10•PEG/PPG-14/7 DIMETHYL
ETHER•SAXIFRAGA SARMENTOSA EXTRACT•SCUTELLARIA BAICALENSIS ROOT
EXTRACT•ECTOIN•SOPHORA ANGUSTIFOLIA ROOT EXTRACT•HYDROGENATED
POLYDECENE•HYDROGEN DIMETHICONE•ISOSTEARIC ACID•DEXTRIN
PALMITATE•ALUMINUM HYDROXIDE•STEARIC ACID•DISTEARDIMONIUM
HECTORITE•SILICA•POLYMETHYLSILSESQUIOXANE•TALC•ALCOHOL•TRISODIUM
EDTA•BHT•SYZYGIUM JAMBOS LEAF EXTRACT•TOCOPHEROL•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 - 100 mL Bottle Carton

SHISEIDO

Anti-Aging Suncare

50+

WetForce

Ultimate

Sun Protection Lotion

BROAD SPECTRUM

SPF 50+

For Face/Body

WATER RESISTANT (80 MINUTES)

SUNSCREEN

100mL 3.3 FL. OZ.



Ultimate Sun Protection Lotion

BROAD SPECTRUM
SPF 50+

For Face/Body



SHISEIDO

Anti-Aging Suncare



50+
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Ultimate
Sun Protection Lotion

BROAD SPECTRUM
SPF 50+

For Face/Body

WATER RESISTANT (80 MINUTES)
SUNSCREEN

100mL 3.3 FL. OZ.

Drug Facts (continued)

Inactive ingredients

WATER • DIMETHICONE • BUTYLENE GLYCOL •
ISOPROPYL MYRISTATE • ISOHEXADECANE •
SD ALCOHOL 40-8 • ISODODECANE •
METHYL METHACRYLATE COPOLYMER •
PEG-8 POLYDIMETHYLSILOXYETHYL DIMETHICONE •
TRIMETHYLSILOXYLICATE •
POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER •
XYLITOL • GLYCERIN • METHYL GLUCETH-10 •
PEG/PPG-14/7 DIMETHYL ETHER •
SAXIFRAGA SARMENTOSA EXTRACT •
SCUTELLARIA BAICALENSIS ROOT EXTRACT •
ECTOIN •
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •
HYDROGENATED POLYDECENE •
HYDROGEN DIMETHICONE • ISOSTEARIC ACID •
DEXTRIN PALMITATE • ALUMINUM HYDROXIDE •
STEARIC ACID • DISTEARDIMONIUM HECTORITE •
SILICA • POLYMETHYLSILSESQUOXANE • TALC •
ALCOHOL • TRISODIUM EDTA • BHT •
SYZYGIUM JAMBOS LEAF EXTRACT •
TOCOPHEROL • FRAGRANCE •

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70.5x37x105.5
 1 2 3 4 5 6 7 8 9 0

SHISEIDO
 ULTIMATE SUN PROTECTION LOTION
 BROAD SPECTRUM SPF 50+
 FOR FACE/BODY

Multi-Environment Defense. Multi-Faceted Skin Protection

Providing powerful protection for your skin, this innovative protective veil actually becomes even more effective when it comes into contact* with water. It also includes skincare ingredients that help prevent skin dryness. It provides high sun protection technology, yet is comfortable and gentle on the skin.

- Broad spectrum UV protection helps reduce the appearance of photo-aging with exclusive SuperVeil-UV 360™ technology.
- Formulated with WetForce technology, which reacts positively to water on contact*, activating additional strength within the protective veil*.
- NON-COMEDOGENIC
- DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED
- * Compared before and after soaking in water for 30 minutes. Be sure to reapply product immediately after water activity such as swimming or after towel-drying skin.

Drug Facts

Active ingredients

Active ingredients	Purpose
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SHISEIDO AMERICAS CORPORATION DIST.
 NEW YORK, NY 10022
 MADE IN U.S.A.
 GLO. 11484
 www.shiseido.com

Drug Facts (continued)

Warnings

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Stop use and ask a doctor if rash occurs

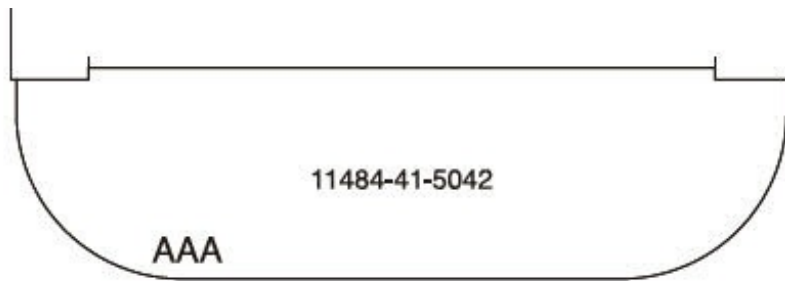
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SHISEIDO ULTIMATE SUN PROTECTION

octinoxate, octocrylene, titanium dioxide, and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	8406 mg in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3408 mg in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1590 mg in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	18630 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOHEXADECANE (UNII: 918X10UF1E)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XYLITOL (UNII: VCQ006KQ1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ECTOINE (UNII: 7GXZ3858RY)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
ISO STEARIC ACID (UNII: X33R8U0062)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
TALC (UNII: 7SEV7J4R1U)	
ALCOHOL (UNII: 3K9958V90M)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-253-10	1 in 1 CARTON	02/01/2015	
1		100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:58411-253-80	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(58411-253) , analysis(58411-253)