

SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR- octinoxate, octocrylene, and zinc oxide lotion
SHISEIDO AMERICA INC.

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 URBAN ENVIRONMENT OIL-FREE UV PROTECTOR CREAM

Drug Facts

<i>ACTIVE INGREDIENTS:</i>	<i>Purpose</i>
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 12.5%	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 40 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, ISODODECANE, SD ALCOHOL 40-B, DIPROPYLENE GLYCOL,

ETHYLHEXYL PALMITATE, PEG-10 DIMETHICONE, GLYCERIN,
POLYMETHYLSILSESQUIOXANE, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE
CROSSPOLYMER, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, DIMETHICONE/VINYL
DIMETHICONE CROSSPOLYMER, XYLITOL, METHYL METHACRYLATE CROSSPOLYMER,
THIOTAURINE, SCUTELLARIA BAICALENSIS ROOT EXTRACT, PAEONIA ALBIFLORA
ROOT EXTRACT, ONONIS SPINOSA ROOT EXTRACT, ECTOIN, LAURYL PEG-9
POLYDIMETHYLSILOXYETHYL DIMETHICONE, HYDROGEN DIMETHICONE, BUTYLENE
GLYCOL, DISODIUM EDTA, DISTEARDIMONIUM HECTORITE, ALUMINA, BHT,
TRIETHOXYCAPRYLYLSILANE, SYZYGIIUM JAMBOS LEAF EXTRACT, TOCOPHEROL,
PHENOXYETHANOL, BENZOIC ACID, FRAGRANCE, TITANIUM DIOXIDE, MICA,

Other information

- protect this product in this container from excessive heat and direct sun.

Questions or comments?

Call toll free 1-800-906-7503

SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
SHISEIDO DIST. NEW YORK • PARIS • MILANO

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

SHISEIDO
GINZA TOKYO

Urban Environment
Oil-Free UV Protector

42

BROAD SPECTRUM
SPF 42

For Face

WATER RESISTANT
(40 MINUTES)

SUNSCREEN

30mL 1 FL. OZ.

Urban Environment Oil-Free UV Protector



BROAD SPECTRUM SPF 42

Drug Facts (continued)

Directions

For sunscreen use:
- apply liberally 15 minutes before sun exposure
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http://s1872.com/14431AA
See our website for more information.

SHISEIDO
GINZA TOKYO

Urban Environment Oil-Free UV Protector

42

BROAD SPECTRUM SPF 42

For Face

WATER RESISTANT (40 MINUTES) SUNSCREEN

30mL 1 FL. OZ.

Drug Facts (continued)

Inactive ingredients

WATER • DIMETHICONE • ISODODECANE • SD ALCOHOL 40-8 • DIPROPYLENE GLYCOL • ETHYLHEXYL PALMITATE • PEG-10 DIMETHICONE • GLYCERIN • POLYMETHYLSILSESQUOXANE • VINYL DIMETHICONE/METHICONE SILSESQUOXANE COPOLYMER • POLYBUTYLENE GLYCOL/PPG-3/1 COPOLYMER • DIMETHICONE/VINYL DIMETHICONE COPOLYMER • XYLITOL • METHYL METHACRYLATE COPOLYMER • THIOCTAURINE • SOUTHELLA BAIJALENSIS ROOT EXTRACT • PAEONIA ALBIFLORA ROOT EXTRACT • ONONIS SPINOSA ROOT EXTRACT • ECTOIN • LAURYL PEG-8 POLYDIMETHYLSILOXYETHYL DIMETHICONE • HYDROGEN DIMETHICONE • BUTYLENE GLYCOL • DISODIUM EDTA • DISTEARDIMONIUM HECTORITE • ALUMINA • BHT • TRITHOXYPYRYLSILANE • SYZYGIUM JAMBOS LEAF EXTRACT • TOCOPHEROL • PHENOXYETHANOL • BENZOIC ACID • FRAGRANCE • TITANIUM DIOXIDE • MICA

Other Information

protect this product in this container from excessive heat and direct sun.

CULTECH INC

003429

SHISEIDO
URBAN ENVIRONMENT OIL-FREE UV PROTECTOR

An ultra-light, oil-free, sun protection lotion for the face that controls excess sebum and gives skin a matte appearance while guarding against daily environmental aggressors. Promotes the natural beauty of skin by helping to prevent oxidation and the skin-damaging effects of sebum.

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

NON-COMEDOGENIC.
 DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.

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SHISEIDO AMERICAS CORPORATION DIST.
 NEW YORK, NY 10022
 MADE IN U.S.A.
 GLO. 14431
 www.shiseido.com

Drug Facts (continued)

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

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14431-41-5040
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SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR

octinoxate, octocrylene, and zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58411-346

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1557 mg in 31.77 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	953 mg in 31.77 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3971 mg in 31.77 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
XYLITOL (UNII: VCQ006KQ1E)	
THIO TAURINE (UNII: NQZ2D7AO62)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ECTOINE (UNII: 7GXZ3858RY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM OXIDE (UNII: LM26O6933)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-346-10	1 in 1 CARTON	10/01/2012	
1		31.77 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:58411-346-80	2.12 g in 1 POUCH; Type 0: Not a Combination Product	10/01/2012	
3	NDC:58411-346-11	1 in 1 CARTON	10/01/2012	

3	7.41 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	10/01/2012	

Labeler - SHISEIDO AMERICA INC. (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-346) , ANALYSIS(58411-346)

Revised: 12/2019

SHISEIDO AMERICA INC.