

**SHISEIDO URBAN ENVIRONMENT UV PROTECTION- octinoxate, 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.*

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**SHISEIDO URBAN ENVIRONMENT UV PROTECTION CREAM**

***Drug Facts***

<b>ACTIVE INGREDIENTS:</b>	<b>Purpose</b>
OCTINOXATE 2.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 10.6%	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, ISODODECANE, CYCLOMETHICONE, DIMETHICONE, BUTYLENE GLYCOL, SD

ALCOHOL 40-B, POLYMETHYL METHACRYLATE, LAURYL PEG-9  
POLYDIMETHYLSILOXYETHYL DIMETHICONE, GLYCERIN, DISTEARDIMONIUM  
HECTORITE, XYLITOL, METHYL GLUCETH-10, PEG/PPG-14/7 DIMETHYL ETHER,  
THIOTAURINE, SCUTELLARIA BAICALENSIS ROOT EXTRACT, ARGININE HCl, ONONIS  
SPINOSA ROOT EXTRACT, ECTOIN, SODIUM PCA, HYDROGENATED POLYDECENE,  
HYDROGEN DIMETHICONE, ISOSTEARIC ACID, BENZOPHENONE-3, TRISODIUM EDTA,  
SILICA, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, ALUMINA,  
TRIETHOXYCAPRYLYLSILANE, BHT, SYZYGIUM JAMBOS LEAF EXTRACT, TOCOPHEROL,  
PHENOXYETHANOL, FRAGRANCE, TITANIUM DIOXIDE,

**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 DIST. NEW YORK • PARIS • MILANO

**PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton**

**SHISEIDO  
GINZA TOKYO**

Urban Environment  
UV Protection Cream

**40**

BROAD SPECTRUM  
SPF 40

For Face/Body

WATER RESISTANT  
(40 MINUTES)

SUNSCREEN

50mL NET WT. 1.9 OZ.

Urban Environment UV Protection Cream



BROAD SPECTRUM SPF 40

**SHISEIDO**  
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### Drug Facts (continued)

#### Directions

- children under 6 months:  
Ask a doctor

#### Inactive ingredients

WATER • ISODODECANE •  
CYCLOMETHICONE • DIMETHICONE •  
BUTYLENE GLYCOL • SD ALCOHOL 40-B •  
POLYMETHYL METHACRYLATE •  
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL  
DIMETHICONE •  
GLYCERIN • DISTEARDIMONIUM HECTORITE •  
XYLITOL • METHYL GLUCETH-10 •  
PEG/PPG-14/7 DIMETHYL ETHER •  
THIOTAURINE •  
SCUTELLARIA BAICALENSIS ROOT EXTRACT •  
ARGININE HCl •  
ONONIS SPINOSA ROOT EXTRACT • ECTOIN •  
SODIUM PCA •  
HYDROGENATED POLYDECENE •  
HYDROGEN DIMETHICONE •  
ISOSTEARIC ACID • BENZOPHENONE-3 •  
TRISODIUM EDTA • SILICA •  
POLYBUTYLENE GLYCOL/PPG-3/1  
COPOLYMER •  
ALUMINA • TRIETHOXYCAPRYLYLSILANE •  
BHT • SYZYGIUM JAMBOS LEAF EXTRACT •  
TOCOPHEROL • PHENOXYETHANOL •  
FRAGRANCE • TITANIUM DIOXIDE •

#### Other Information

- protect this product in this  
container from excessive  
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Questions or Comments?  
Call toll free 1-800-906-7503

50mL NET WT. 1.9 OZ.

CULTECH INC

SHISEIDO  
URBAN ENVIRONMENT UV PROTECTION CREAM  
BROAD SPECTRUM SPF 40  
FOR FACE/BODY

A feather-light daily sunscreen that provides exceptional hydration while protecting against external aggressors such as UV rays, dryness and air pollution for beautiful, healthy-looking skin.

- Exceptionally powerful formula effectively helps protect skin from harmful UVA/UVB rays that cause photo-aging.
- Hydro-Restoring Complex contains moisturizing amino acids that naturally exist in skin. Provides long-lasting moisture for skin that is smooth to the touch.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC.  
DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.

### Drug Facts

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ZINC OXIDE 10.6% .....	Sunscreen

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■ reapply:

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■ 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

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skin cancer and early skin aging caused by the sun

### Warnings

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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. 14432  
[www.shiseido.com](http://www.shiseido.com)



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/14432AA>

See our website for more information.

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AAA

## SHISEIDO URBAN ENVIRONMENT UV PROTECTION

octinoxate, octocrylene, and zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-347
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1583 mg in 54.6 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1638 mg in 54.6 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5788 mg in 54.6 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>METHYL GLUCETH-10</b> (UNII: N0MWT4C7WH)	
<b>THIO TAURINE</b> (UNII: NQZ2D7AO62)	
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)	
<b>ARGININE HYDRO CHLORIDE</b> (UNII: F7LTH1E20Y)	
<b>ONONIS SPINOSA ROOT</b> (UNII: FD2FMC53M1)	
<b>ECTOINE</b> (UNII: 7GXZ3858RY)	
<b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)	
<b>HYDROGENATED POLYDECENE (550 MW)</b> (UNII: U333RI6EB7)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SYZYGIUM JAMBOS LEAF</b> (UNII: 407Z4W5LFF)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-347-80	2.18 g in 1 POUCH; Type 0: Not a Combination Product	10/01/2012	
2	NDC:58411-347-60	1 in 1 CARTON	10/01/2012	
2		54.6 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:58411-347-61	1 in 1 CARTON	10/01/2012	
3		7.64 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:58411-347-62	1 in 1 CARTON	10/01/2012	
4		16.38 g 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 NOT FINAL	part352	10/01/2012	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

## Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-347) , ANALYSIS(58411-347)

Revised: 12/2019

SHISEIDO AMERICAS CORPORATION