

**SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR- zinc oxide, homosalate, octocrylene, and octisalate emulsion**  
**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 URBAN ENVIRONMENT OIL-FREE UV PROTECTOR**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
HOMOSALATE 5.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 5.0%	Sunscreen
ZINC OXIDE 9.7%	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 40 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
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

### **Inactive Ingredients**

WATER•ISODODECANE•DIMETHICONE•SD ALCOHOL 40-B•DIPROPYLENE GLYCOL•ETHYLHEXYL PALMITATE•PEG-10 DIMETHICONE•GLYCERIN•POLYMETHYLSILSESQUIOXANE•VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER•POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER•XYLITOL•SILICA•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•TOCOPHEROL•ALUMINUM HYDROXIDE•TRIETHOXYCAPRYLYLSILANE•SODIUM METABISULFITE•SYZYGIUM JAMBOS LEAF EXTRACT•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

### **PRINCIPAL DISPLAY PANEL - 50 mL Bottle Carton**

SHISEIDO  
GINZA TOKYO

Urban Environment  
Oil-Free UV Protector

42

BROAD SPECTRUM  
SPF 42

For Face

WATER RESISTANT  
(40 MINUTES)

SUNSCREEN

50mL 1.6 FL. OZ.

Urban Environment Oil-Free UV Protector



BROAD SPECTRUM SPF 42

SHISEIDO  
GINZA TOKYO

Urban Environment  
Oil-Free UV Protector

42

BROAD SPECTRUM  
SPF 42

For Face

WATER RESISTANT  
(40 MINUTES)  
SUNSCREEN

50mL 1.6 FL. OZ.

#### Drug Facts (continued)

#### Directions

■ children under 6 months: Ask a doctor

#### Inactive ingredients

WATER • ISODODECANE • DIMETHICONE •  
SD ALCOHOL 40-8 • DIPROPYLENE GLYCOL •  
ETHYLHEXYL PALMITATE • PEG-10 DIMETHICONE •  
GLYCERIN • POLYMETHYLSILOXANE •  
VINYL DIMETHICONE/METHICONE/SILOXANE  
CROSSPOLYMER •  
POLYBUTYLENE GLYCOL/PPG-8/1 COPOLYMER •  
XYLITOL • SILICA •  
METHYL METHACRYLATE CROSSPOLYMER •  
THIOCTAURINE •  
SCUTELLARIA BANCALENSIS ROOT EXTRACT •  
PAEONIA ALBIFLORA ROOT EXTRACT •  
ONONIS SPINOSA ROOT EXTRACT • ECTOIN •  
LAURYL PEG-8 POLYDIMETHYLSILOXYETHYL  
DIMETHICONE •  
HYDROGEN DIMETHICONE • BUTYLENE GLYCOL •  
DISODIUM EDTA • DISTEAROYMONIUM HECTORITE •  
TOCOPHEROL • ALUMINUM HYDROXIDE •  
TRIETHOXYCAPRYLSILANE • SODIUM METABISULFATE •  
SYZYGIUM JAMBOS LEAF EXTRACT •  
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  
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.

### Drug Facts

Active ingredients	Purpose
HOMOSALATE 5.0% .....	Sunscreen
OCTISALATE 5.0% .....	Sunscreen
OCTOCRYLENE 5.0% .....	Sunscreen
ZINC OXIDE 9.7% .....	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 ▶

Specially formulated by  
Shiseido Laboratories, Japan.  
SHISEIDO AMERICAS CORPORATION DIST.  
NEW YORK, NY 10017  
MADE IN U.S.A.  
GLO. 14483



### Drug Facts (continued)

#### Warnings

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

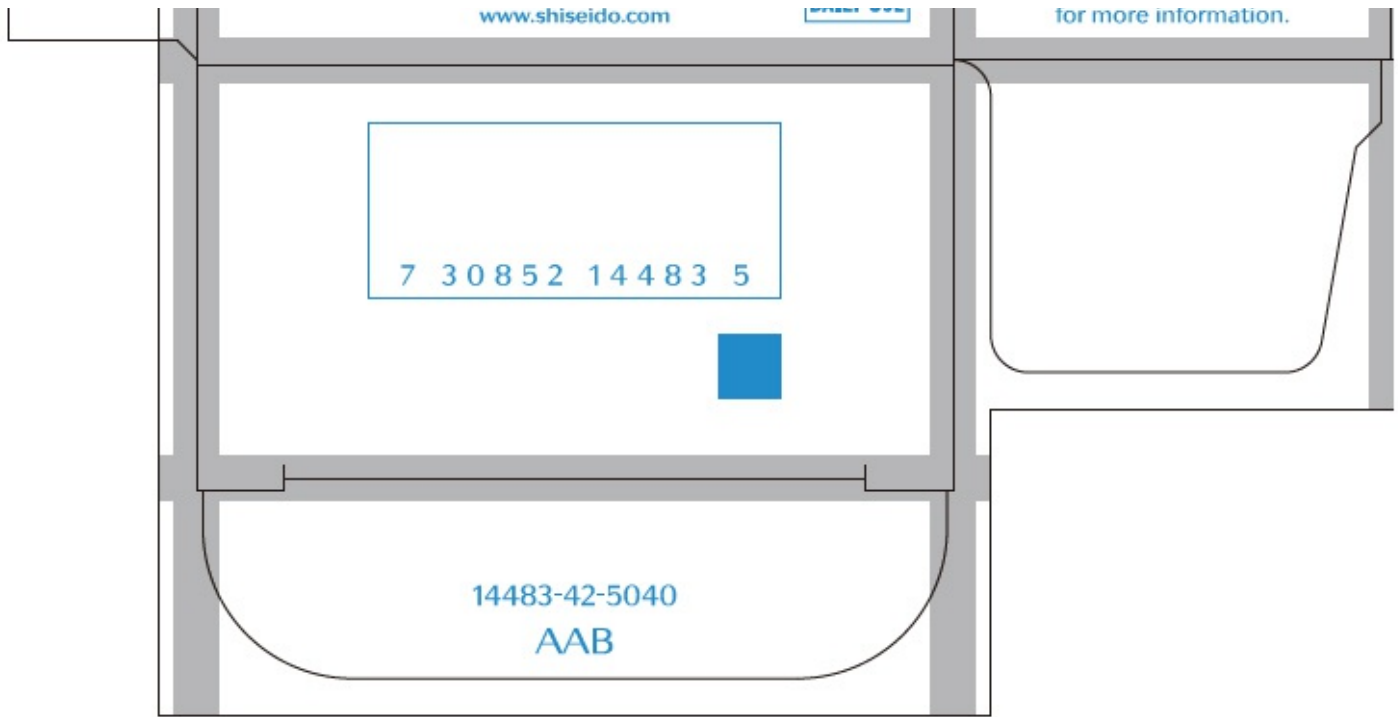
#### Directions

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

<http://s1872.com/14483AA>

See our website



## SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR

zinc oxide, homosalate, octocrylene, and octisalate emulsion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-627
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.16 g in 50 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2.65 g in 50 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	2.65 g in 50 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.65 g in 50 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	

<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)
<b>XYLITOL</b> (UNII: VCQ006KQ1E)
<b>METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER</b> (UNII: EG97988M5Q)
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>THIOTAURINE</b> (UNII: NQZ2D7AO62)
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)
<b>MICA</b> (UNII: V8A1AW0880)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>PAEONIA LACTIFLORA ROOT</b> (UNII: 3Z3866YW6P)
<b>ECTOINE</b> (UNII: 7GXZ3858RY)
<b>SYZYGIIUM JAMBOS LEAF</b> (UNII: 407Z4W5LFF)
<b>ONONIS SPINOSA ROOT</b> (UNII: FD2FMC53M1)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-627-60	1 in 1 CARTON	01/01/2021	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58411-627-61	1 in 1 CARTON	01/01/2021	
2		30 mL in 1 TUBE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2021	

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