

**SHISEIDO URBAN ENVIRONMENT VITA-CLEAR SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene 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.*

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**SHISEIDO URBAN ENVIRONMENT VITA-CLEAR SUNSCREEN SPF 42**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
AVOBENZONE 2.3%	Sunscreen
HOMOSALATE 10.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 5.0%	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 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 value 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**

TRISILOXANE □ WATER □ DIISOPROPYL SEBACATE □ SILICA □ GLYCERIN □ ALCOHOL DENAT. □ ISODODECANE □ PEG/PPG-9/2 DIMETHYL ETHER □ LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE □ TRIMETHYLSILOXYSILICATE □ DEXTRIN PALMITATE □ DISTEARDIMONIUM HECTORITE □ TREHALOSE □ PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE □ PHYTOSTERYL MACADAMIATE □ SODIUM CHLORIDE □ 2-O-ETHYLASCORBIC ACID □ AMINOETHANESULFINIC ACID □ DIPOTASSIUM GLYCYRRHIZATE □ PANTHENYL ETHYL ETHER □ SODIUM POLYACRYLATE □ TOCOPHERYL ACETATE □ SODIUM HYALURONATE □ SANGUISORBA OFFICINALIS ROOT EXTRACT □ CAMELLIA SINENSIS LEAF EXTRACT □ GARCINIA MANGOSTANA BARK EXTRACT □ PERILLA OCYMOIDES LEAF EXTRACT □ SPIRULINA PLATENSIS EXTRACT □ DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER □ BUTYLENE GLYCOL □ SILICA DIMETHYL SILYLATE □ TRISODIUM EDTA □ TOCOPHEROL □ BHT □ ALCOHOL □ SODIUM METABISULFITE □ ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT □ BARIUM SULFATE □ SODIUM CITRATE □ 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 - 30 mL Bottle Carton**

SHISEIDO  
GINZA TOKYO

Urban Environment

VITA-CLEAR

with VITAMIN C

SPF  
42

BROAD SPECTRUM SPF 42  
WATER RESISTANT (40 MINUTES)  
SUNSCREEN

30mL 1 FL. OZ.

Urban Environment  
Vita-Clear Sunscreen  
BROAD SPECTRUM SPF 42



SHISEIDO  
GINZA TOKYO

Urban Environment  
VITA-CLEAR

with VITAMIN C

SPF  
42

BROAD SPECTRUM SPF 42  
WATER RESISTANT (40 MINUTES)  
SUNSCREEN

30mL 1 FL. OZ.

**Drug Facts (continued)**

**Inactive ingredients**

TRISILOXANE • WATER • ISOPROPYL SEBACATE • SILICA • GLYCERYL ALCOHOL DECA-1,3-DIOLEATE • ISODODECANE • PEG-12 DIMETHYL ETHER LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • TRIMETHYLSILOXYSEBACATE • DEXTRAN PALMITATE • DOSTEARCHINONOLIN HEPTOATE • TREHALOSE • PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • PHYCOSTERYL MACADAMATE • SODIUM CHLORIDE • 2-ETHYL ASCORBIC ACID • AMINODIPROPANESULFONIC ACID • DIPOSSA SODIUM GLYCERYL SEBACATE • PANTHENYL ETHER • SODIUM POLYACRYLATE • TOCOPHERYL ACETATE • SODIUM HYALURONATE • SANGUISORBA OFFICINALIS ROOT EXTRACT • CAMELLIA SINENSIS LEAF EXTRACT • GARDONIA MANGOSTANA BARK EXTRACT • PERILLA OCYMOIDES LEAF EXTRACT • SPERULLA PLATENSIS EXTRACT • DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLAURATE CROSSPOLYMER • BUTYLENE GLYCOL • SILICA DIMETHYL SILYLATE • TRISODIUM EDTA • TOCOPHEROL • BHT • ALCOHOL • SODIUM METABISULFITE • ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT • BARIUM SULFATE • SODIUM CITRATE • 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

<N05943-81>

<http://s1872.com/19547AA>  
See our website for more information.

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1 2 3 4 5 6 7 8 9 0

SHISEIDO  
URBAN ENVIRONMENT  
VITA-CLEAR SUNSCREEN  
BROAD SPECTRUM SPF 42

Lightweight, invisible daily sunscreen for effective dual care. Protects against UV rays and brings out a moisturized, bright look.

✓ Seamlessly protects against harmful UVA/UVB rays—the main cause of sun spots and pollution.\*

2 Infused with Vitamin C. Experience more elasticity, brightness and deep moisture.\*\*

For bright, hydrated skin, 365 days a year.

\*Shake well before use.

\*\*Product color may darken with temperature changes. This will not affect product quality.

NO OXYBENZONE • NO OCTINOXATE • NO PARABENS • NO CYCLIC SILICONE • NON-COMEDOGENIC • DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED

\*microtest \*\*goldermis

**Drug Facts**

Active ingredients	Purpose
AVOBENZONE 2.3%	Sunscreen
HOMOSALATE 10.0%	
OCTISALATE 5.0%	
OCTOCRYLENE 5.0%	

**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

Specifically formulated by Shiseido Laboratories, Japan.



**Drug Facts (continued)**

**Warnings**

**For external use only**

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**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:

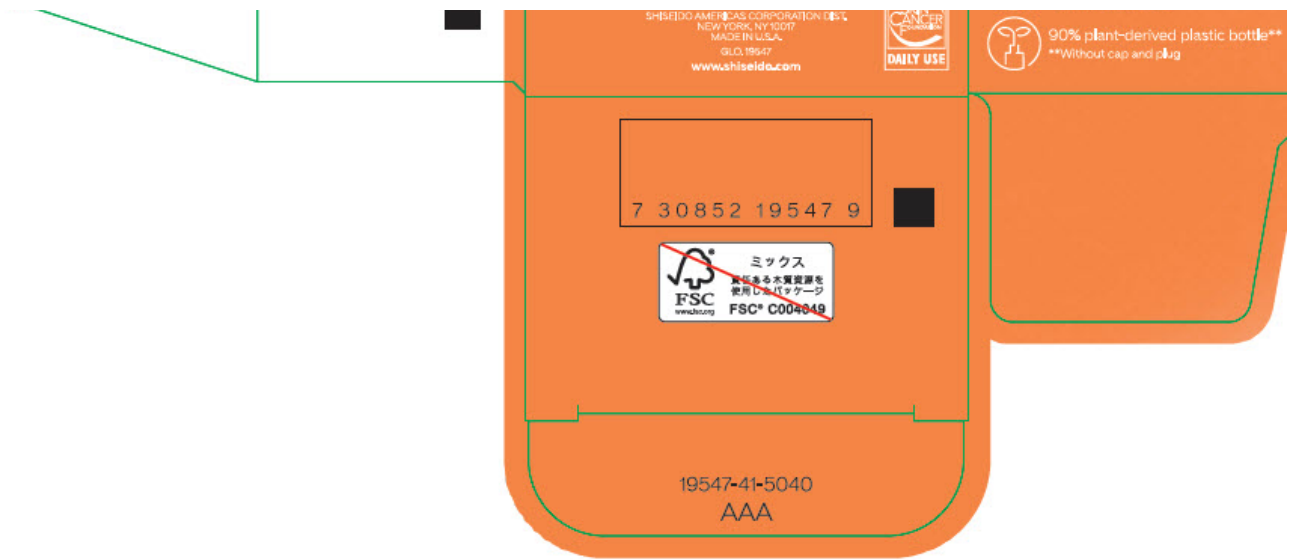
- apply liberally 15 minutes before sun exposure
- reapply:
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours

■ **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. to 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor



Less elution\*  
\*Comparing to Shiseido non-water resistant sunscreens



## SHISEIDO URBAN ENVIRONMENT VITA-CLEAR SUNSCREEN

avobenzone, homosalate, octisalate, and octocrylene emulsion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-854
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	690 mg in 30 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	3000 mg in 30 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1500 mg in 30 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1500 mg in 30 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>PEG/PPG-9/2 DIMETHYL ETHER</b> (UNII: LM6Q66468X)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>TREHALOSE</b> (UNII: B8WCK70T7I)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>PHYTOSTERYL MACADAMIATE</b> (UNII: 233VSF903M)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

<b>2-O-ETHYL ASCORBIC ACID</b> (UNII: 801M14RK9K)
<b>HYPOTAURINE</b> (UNII: 5L08GE4332)
<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)
<b>PANTHENYL ETHYL ETHER</b> (UNII: F4WMF8NX3B)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)
<b>SANGUISORBA OFFICINALIS ROOT</b> (UNII: 4NYV2HT01X)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>GARCINIA MANGOSTANA BARK</b> (UNII: N6A4WY566I)
<b>PERILLA FRUTESCENS LEAF</b> (UNII: T4L5881Y68)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>SILICA DIMETHYL SILYLATE</b> (UNII: EU2PSP0G0W)
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>BARIUM SULFATE</b> (UNII: 25BB7EKE2E)
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-854-20	1 in 1 BOX	08/01/2022	
1	NDC:58411-854-40	30 mL in 1 BOTTLE, PLASTIC; 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	12/25/2021	

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

Revised: 8/2022

SHISEIDO AMERICAS CORPORATION