

SHISEIDO URBAN ENVIRONMENT VITA-CLEAR SUNSCREEN- avobenzone, homosalate, octisalate, and octocrylene emulsion
SHISEIDO AMERICAS CORPORATION

SHISEIDO URBAN ENVIRONMENT VITA-CLEAR SUNSCREEN SPF 42

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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 POLYDIMETHYSILOXYETHYL 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 DECAHYDRATE • ISODODECANE • PEG-12 DIMETHYL ETHER LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • TRIMETHYLSILOXYSEBACATE • DEXTRAN PALMITATE • DOSTEARDINONUM HECTOATE • TREHALOSE • PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • PHYCOSTERYL MACADAMATE • SODIUM CHLORIDE • 2-ETHYL ASCORBIC ACID • AMINODIPROPANESULFONIC ACID • DIPOSSUM 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

<N06943-81>

<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.

1. 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 **goldmet

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

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Stop use and ask a doctor if rash occurs

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Flammable: Do not use near heat, flame, or while smoking.

Directions

For sunscreen use:

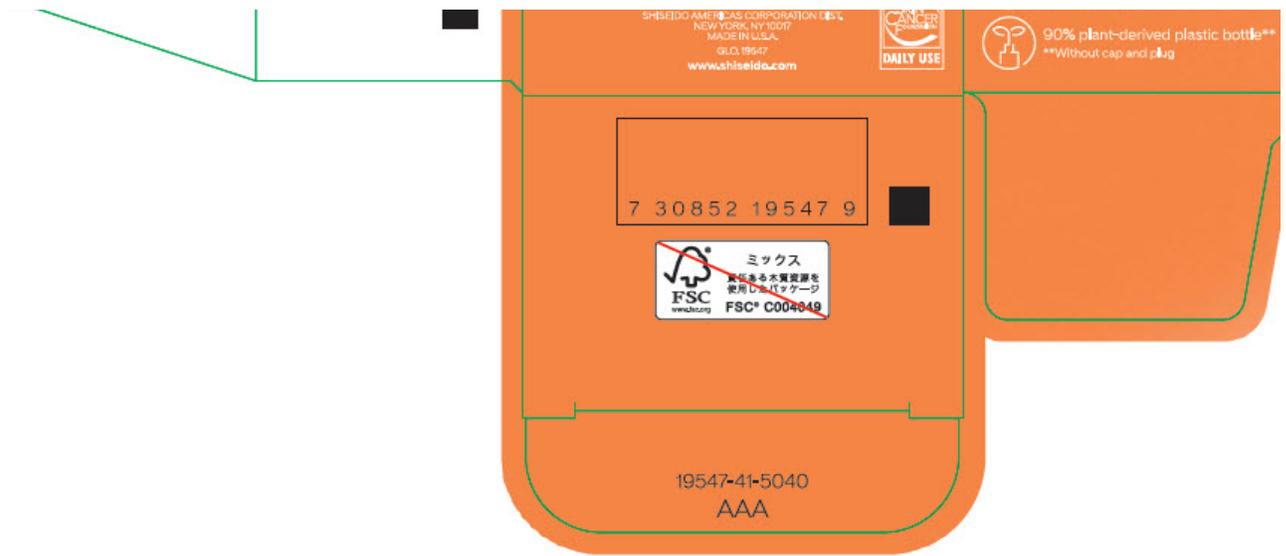
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- reapply:
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 - immediately after towel drying
 - at least every 2 hours

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- 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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)
HYPOTAURINE (UNII: 5L08GE4332)
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)
PANTHENYL ETHYL ETHER (UNII: F4WMF8NX3B)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SANGUISORBA OFFICINALIS ROOT (UNII: 4NYV2HT01X)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
EDETATE TRISODIUM (UNII: 420IP921MB)
TOCOPHEROL (UNII: R0ZB2556P8)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
ROSEMARY (UNII: IJ67X351P9)
BARIUM SULFATE (UNII: 25BB7EKE2E)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
PHENOXYETHANOL (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 Drug	M020	12/25/2021	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
Shiseido America Inc.		782677132	analysis(58411-854) , manufacture(58411-854)