

SHISEIDO URBAN ENVIRONMENT OIL-FREE SUNSCREEN SPF 42- ensulizole, homosalate, octisalate, and zinc oxide 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 SUNSCREEN SPF 42

Drug Facts

Active ingredients	Purpose
ENSULIZOLE 1.0%	Sunscreen
HOMOSALATE 15.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
ZINC OXIDE 15.5%	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.

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. – 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

WATER ■ DIMETHICONE ■ TRISILOXANE ■ SD ALCOHOL 40-B ■ ZINC OXIDE ■ GLYCERIN ■ SILICA ■ PEG/PPG-14/7 DIMETHYL ETHER ■ LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE ■ PEG-10 DIMETHICONE ■ TREHALOSE ■ MYRISTYL MYRISTATE ■ ETHYLHEXYL PALMITATE ■ DEXTRIN PALMITATE ■ ISODECYL NEOPENTANOATE ■ ASCORBYL TETRAISOPALMITATE ■ THIOTAURINE ■ DIPOTASSIUM GLYCYRRHIZATE ■ SCUTELLARIA BAICALENSIS ROOT EXTRACT ■ PAEONIA ALBIFLORA ROOT EXTRACT ■ SODIUM HYALURONATE ■ SANGUISORBA OFFICINALIS ROOT EXTRACT ■ CAMELLIA SINENSIS LEAF EXTRACT ■ GARCINIA MANGOSTANA BARK EXTRACT ■ PERILLA OCYMOIDES LEAF EXTRACT ■ SPIRULINA PLATENSIS EXTRACT ■ TRIETHANOLAMINE ■ TRIETHOXYCAPRYLYLSILANE ■ BUTYLENE GLYCOL ■ DISODIUM EDTA ■ DISTEARDIMONIUM HECTORITE ■ TOCOPHEROL ■ BHT ■ ALCOHOL ■ ISOSTEARIC ACID ■ MENTHOXYPROPANEDIOL ■ SODIUM METABISULFITE ■ POLYSILICONE-2 ■ BARIUM SULFATE ■ SODIUM CITRATE ■ PHENOXYETHANOL ■ BENZOIC ACID ■ FRAGRANCE ■ IRON OXIDES ■

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

Sun Dual Care™

OIL-FREE
with HYALURONIC ACID

SPF
42

BROAD SPECTRUM SPF 42
WATER RESISTANT (40 MINUTES)
SUNSCREEN

30mL 1 FL. OZ.

Urban Environment
Oil-Free Sunscreen
BROAD SPECTRUM SPF 42



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OIL-FREE
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BROAD SPECTRUM SPF 42
WATER RESISTANT (40 MINUTES)
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Drug Facts (continued)

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Less elution*

*Comparing to Shiseido non-water resistant sunscreens



90% plant-derived bottle**

**Without cap and plug

Drug Facts (continued)

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Questions or Comments?

Call toll free 1-800-906-7503

<M100412-811>



<http://s1872.com/18209AA>
See our website
for more information.

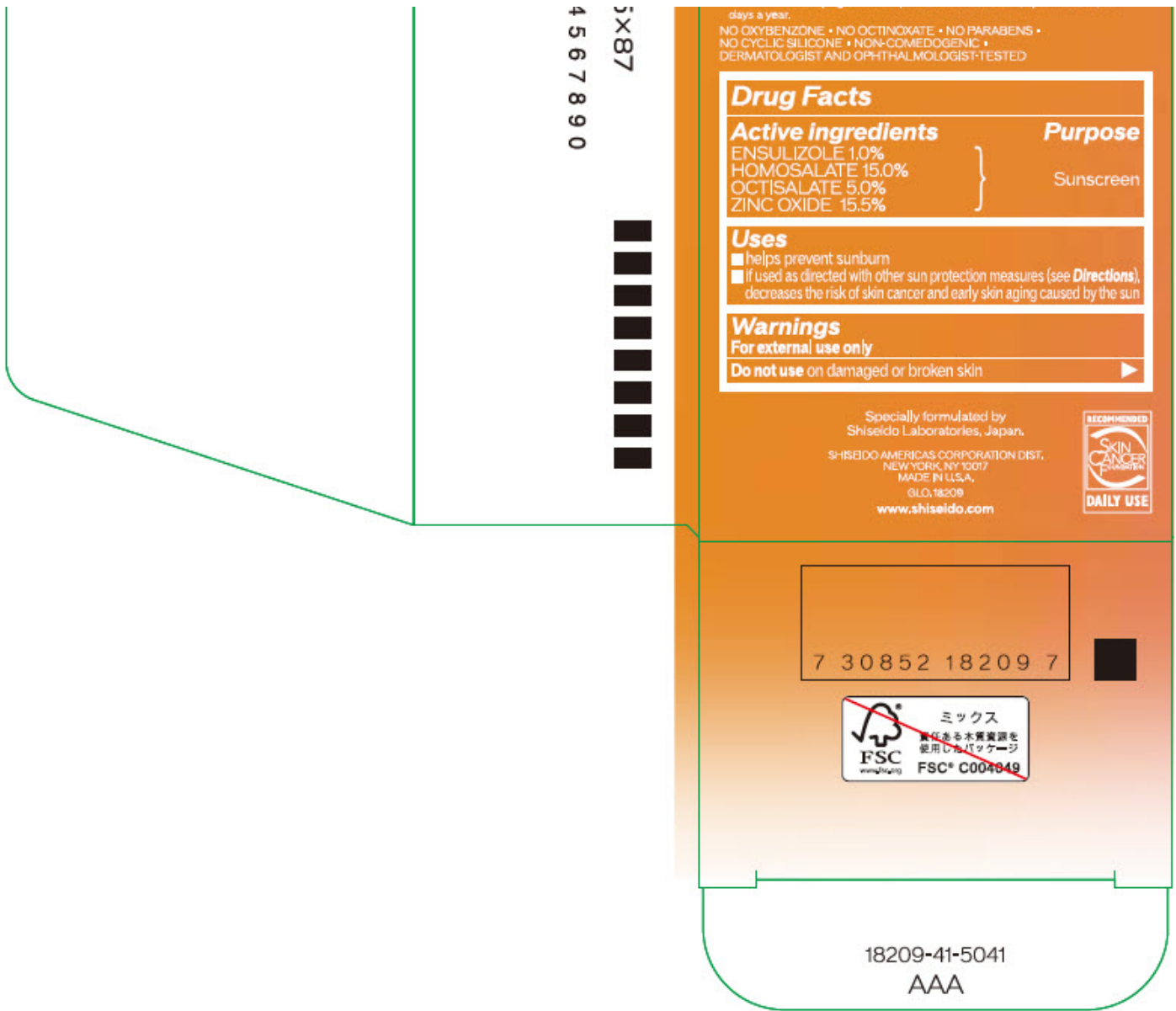
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SHISEIDO
URBAN ENVIRONMENT
OIL-FREE SUNSCREEN
BROAD SPECTRUM SPF 42

Powered by Sun Dual Care™ infused with Hyaluronic Acid.
To protect skin from UV rays, and boost hydration.

1. Seamlessly protects against harmful UVA/UVB and pollution.
2. Amplifies the helpful power of sunlight and supports skin's inner hydration ability. Dehydrated skin is instantly replenished.

• Oil-free and mattifying. Powerful protection. For smooth, hydrated skin. 365



SHISEIDO URBAN ENVIRONMENT OIL-FREE SUNSCREEN SPF 42
 ensulizole, homosalate, octisalate, and zinc oxide emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-670
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	0.4 g in 30 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.4 g in 30 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.8 g in 30 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.6 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRISILOXANE (UNII: 9G1ZW13R0G)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TREHALOSE (UNII: B8WCK70T7I)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
ASCORBYL TETRAISOPALMITATE (UNII: 47143LT58A)	
THIOTAURINE (UNII: NQZ2D7AO62)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SANGUISORBA OFFICINALIS ROOT (UNII: 4NYV2HT01X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
3-((L-MENTHYL)OXY)PROPANE-1,2-DIOL (UNII: KD6TZ2QICH)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-670-10	1 in 1 CARTON	01/01/2022	
1		30 mL in 1 BOTTLE; 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	01/01/2022	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 11/2021

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