

SHISEIDO ESSENTIAL ENERGY DAY- avobenzone, homosalate, octinoxate, octocrylene, and oxybenzone 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.

SHISEIDO ESSENTIAL ENERGY DAY CREAM

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
AVOBENZONE 2.0%	Sunscreen
HOMOSALATE 5.0%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
OXYBENZONE 1.5%	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.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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·DIPROPYLENE GLYCOL·BETAINE·BUTYLENE GLYCOL·GLYCERIN·BEHENYL ALCOHOL·SD ALCOHOL 40-

B·DIMETHICONE·ISODODECANE·ISOHEXADECANE·BEHENETH-20·SILICA·MYRISTYL MYRISTATE·PHYTOSTERYL MACADAMIATE·ERYTHRITOL·XANTHAN GUM·TOCOPHERYL ACETATE·PEG/PPG-14/7 DIMETHYL ETHER·PEG/PPG-17/4 DIMETHYL ETHER·CAFFEINE·SCUTELLARIA BAICALENSIS ROOT EXTRACT·ANGELICA KEISKEI LEAF/STEM EXTRACT·SODIUM ACETYLATED HYALURONATE·CAMELLIA SINENSIS LEAF EXTRACT·CITRUS UNSHIU PEEL EXTRACT·ZINGIBER AROMATICUS EXTRACT·HYDROLYZED CONCHIOLIN PROTEIN·POLYQUATERNIUM-51·PYROLA INCARNATA EXTRACT·PANAX GINSENG ROOT EXTRACT·PPG-17·STEARYL ALCOHOL·BEHENETH-30·ALCOHOL·DISODIUM EDTA·CARBOMER·CELLULOSE GUM·BHT·SODIUM METAPHOSPHATE·POTASSIUM HYDROXIDE·SODIUM METABISULFITE·TOCOPHEROL·HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER·CINNAMOMUM CASSIA BARK EXTRACT·PHENOXYETHANOL·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 - 50 mL Jar Carton

**SHI SEIDO
GINZA TOKYO**

Essential Energy
Day Cream

BROAD SPECTRUM
SPF 20
SUNSCREEN

ReNeura Technology™

50mL NET WT. 1.7 OZ.

Essential Energy
Day Cream



SHISEIDO

GINZA TOKYO

Essential Energy

Day Cream

BROAD SPECTRUM

SPF 20

SUNSCREEN

ReNeura Technology™

50mL NET WT. 1.7 OZ.

Drug Facts (continued)

Directions

■ children under 6 months: ask a doctor.

Inactive ingredients

WATER - DIPROPYLENE GLYCOL - BEZAMINE - BUTYLENE GLYCOL - GLYCERIN - BEHEXYL ALCOHOL - SD ALCOHOL 40-1
DIMETHICONE - DODECANE - DODECANE - DODECANE - BEHEXYL-20 - SODIUM - MYRISTYL MYRISTATE -
PHYTYL ESTER MAGADANATE - ERYTHRITOL - MANGHAM GUM - TOCOPHERYL ACETATE - PEG-PPG-14/7 DIMETHYL ETHER -
PEG-PPG-14 DIMETHYL ETHER - CAFFEINE - SCUTELLARIA BAIJALENSIS ROOT EXTRACT -
ANGELICA KWANZON LEAF STEM EXTRACT - SODIUM ACETYLATED HYALURONATE - CAMELLIA SINENSIS LEAF EXTRACT -
CITRUS LINDA PEEL EXTRACT - ZINGIBER AROMATICUS EXTRACT - HYDROLYZED CONDENSOLIN PROTEIN - POLYDATERMIDANOL
PYROLA INCARNATA EXTRACT - PINNAX GINGENSIS ROOT EXTRACT - PPG-47 - STEARYL ALCOHOL - BEHEXYL-20 - ALCOHOL -
SODIUM CITRATE - CARBOMER - CELLULOSE GUM - BHT - SODIUM METAPHOSPHATE - POTASSIUM HYDROXIDE - SODIUM
METABISULFITE - TOCOPHEROL - HEPTAMETHYLL HEVYLACTONE CROSSPOLYMER - QUINQUAMMUM CASSIN BARK EXTRACT -
PHENOXETHANOL - FRAGRANCE - IRON OXIDES

Other Information

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Questions or Comments?

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<http://s1872.com/14323AA>
See our website for more
information.

SHISEIDO
ESSENTIAL ENERGY
DAY CREAM
BROAD SPECTRUM SPF 20

Turn your skin's energy back on. Get your skin's glow on.

Focus on the neuroscience of your skin's senses. This silky smooth cream features ReNeura Technology™, to make skin optimally responsive to its skincare benefits. Visible and even subtle aging signs are counteracted. Your skin is luminous, fully hydrated, and protected against hazards throughout the day.

• Apply morning after cleanser.

• Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC. DERMATOLOGIST-TESTED.

Drug Facts

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Specialy formulated by Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
C.I.O. 14323
www.shiseido.com

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14323-41-5040

AAA

Drug Facts (continued)

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- reapply 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.

avobenzone, homosalate, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-364
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1020 mg in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	2550 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3773 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	1530 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	765 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BETAINE (UNII: 3SCV180C9W)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DOCOSANOL (UNII: 9G1OE216XY)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
ISOHEXADECANE (UNII: 918X10UF1E)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
ERYTHRITOL (UNII: RA96B954X6)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPIEW8)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
CAFFEINE (UNII: 3G6A5W338E)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ANGELICA KEISKEI TOP (UNII: AP628M4TQO)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TANGERINE PEEL (UNII: JU3D414057)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
PPG-17 (UNII: OV0Q322E0U)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
BEHENETH-30 (UNII: 21Z34J9KN8)	
ALCOHOL (UNII: 3K9958V90M)	

EDETATE DISODIUM (UNII: 7FLD91C86K)
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)
CHINESE CINNAMON (UNII: WS4CQ062KM)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-364-50	1 in 1 CARTON	02/01/2018	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2018	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-364) , analysis(58411-364)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION