

SHISEIDO FUTURE SOLUTION LX UNIVERSAL DEFENSE E- octisalate, octocrylene, and zinc oxide 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 FUTURE SOLUTION LX UNIVERSAL DEFENSE E

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Octisalate 5.0%	Sunscreen
Octocrylene 7.0%	Sunscreen
Zinc Oxide 15.4%	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 80 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
 - children under 6 months: Ask a doctor

Inactive Ingredients

WATER ▪ ISODODECANE ▪ CAPRYLYL METHICONE ▪ SD ALCOHOL 40-B ▪ BUTYLENE GLYCOL ▪ GLYCERIN ▪ DIMETHICONE ▪ PEG-60 HYDROGENATED CASTOR OIL ▪ TOCOPHERYL ACETATE ▪ 2-O-ETHYL ASCORBIC ACID ▪ PRUNUS SPECIOSA LEAF EXTRACT ▪ ANGELICA ACUTILOBA ROOT EXTRACT ▪ SCUTELLARIA BAICALENSIS ROOT EXTRACT ▪ RUBUS IDAEUS (RASPBERRY) FRUIT EXTRACT ▪ SODIUM ACETYLATED HYALURONATE ▪ ISODONIS JAPONICUS LEAF/STALK EXTRACT ▪ CAMELLIA SINENSIS LEAF EXTRACT ▪ ROSA ROXBURGHII FRUIT EXTRACT ▪ POLYQUATERNIUM-51 ▪ POLYMETHYL METHACRYLATE ▪ PPG-17 ▪ HDI/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER ▪ ISOSTEARIC ACID ▪ PEG-100 HYDROGENATED CASTOR OIL ▪ C30-45 ALKYL METHICONE ▪ DIMETHYLACRYLAMIDE/SODIUM ACRYLOYLDIMETHYLTAURATE CROSSPOLYMER ▪ C30-45 OLEFIN ▪ SORBITAN SESQUIISOSTEARATE ▪ HYDROGEN DIMETHICONE ▪ TRIETHOXYCAPRYLYLSILANE ▪ CELLULOSE GUM ▪ SODIUM METAPHOSPHATE ▪ SUCCINOGLYCAN ▪ CITRIC ACID ▪ ALCOHOL ▪ SILICA ▪ BHT ▪ TOCOPHEROL ▪ DISODIUM EDTA ▪ HYDROXYPROPYL METHYLCELLULOSE STEAROXY ETHER ▪ ALUMINA ▪ SODIUM METABISULFITE ▪ SODIUM CITRATE ▪ TALC ▪ PEG-12 DIMETHICONE ▪ DISODIUM PHOSPHATE ▪ BARIUM SULFATE ▪ ERGOTHIONEINE ▪ SODIUM PHOSPHATE ▪ PHENOXYETHANOL ▪ FRAGRANCE ▪ TITANIUM DIOXIDE ▪ MICA ▪ 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 Tube Carton

SHISEIDO
GINZA TOKYO

FUTURE SOLUTION LX
Universal Defense

SkingenecellEnmei

BROAD SPECTRUM
SPF 50+

WATER RESISTANT (40 MINUTES)
SUNSCREEN

50mL NET WT. 1.7 OZ.

Universal Defense



SHISEIDO
GINZA TOKYO

FUTURE SOLUTION LX

Universal Defense

SkingenecellEnmei

BROAD SPECTRUM
SPF 50+

WATER RESISTANT (40 MINUTES)
SUNSCREEN

Drug Facts (continued)

Inactive ingredients

WATER · ISODODECANE ·
CAPRYLYL METHICONE · SD ALCOHOL 40-8 ·
BUTYLENE GLYCOL · GLYCERIN ·
DIMETHICONE ·
PEG-60 HYDROGENATED CASTOR OIL ·
TOCOPHERYL ACETATE ·
2-O-ETHYL ASCORBIC ACID ·
PRUNUS SPECIOSA LEAF EXTRACT ·
ANGELICA ACUTILoba ROOT EXTRACT ·
SCUTELLARIA BAICALENSIS ROOT EXTRACT ·
RUBUS IDAEUS (RASPBERRY) FRUIT EXTRACT ·
SODIUM ACETYLATED HYALURONATE ·
ISODONIS JAPONICUS LEAF/STALK EXTRACT ·
CAMELLIA SINENSIS LEAF EXTRACT ·
ROSA ROXBURGHII FRUIT EXTRACT ·
POLYQUATERNIUM-51 ·
POLYMETHYL METHACRYLATE · PPG-17 ·
HDI/TRIMETHYLOL HEXYLACTONE
CROSSPOLYMER ·
ISOSTEARIC ACID ·
PEG-100 HYDROGENATED CASTOR OIL ·
C30-45 ALKYL METHICONE ·
DIMETHYLACRYLAMIDE/SODIUM
ACRYLOYLDIMETHYLAURATE
CROSSPOLYMER ·
C30-45 OLEFIN ·
SORBITAN SESQUISOSTEARATE ·
HYDROGEN DIMETHICONE ·
TRIETHOXYCAPRYLYLSILANE ·
CELLULOSE GUM ·
SODIUM METAPHOSPHATE ·
SUCCINOGLYCAN · CITRIC ACID · ALCOHOL ·
SILICA · BHT · TOCOPHEROL ·
DISODIUM EDTA ·
HYDROXYPROPYL METHYLCELLULOSE
STEAROXY ETHER ·
ALUMINA · SODIUM METABISULFITE ·
SODIUM CITRATE · TALC ·
PEG-12 DIMETHICONE ·
DISODIUM PHOSPHATE · BARIUM SULFATE ·
ERGOThIONEINE · SODIUM PHOSPHATE ·

50mL NET WT. 1.7 OZ.

PHENOXYETHANOL • FRAGRANCE •
TITANIUM DIOXIDE • MICA • IRON OXIDES •

Other Information

■ protect this product in this container from excessive heat and direct sun.

Questions or Comments?

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SHISEIDO
FUTURE SOLUTION LX
UNIVERSAL DEFENSE E
BROAD SPECTRUM
SPF 50+

Treasure the life in your skin.

A luxurious daytime protective cream that helps renew skin's vitalizing forces. Features Aggressor Control Technology, for exceptional defense against damage caused by environmental factors that can shock skin out of balance, like photo-environmental radicals*, UV rays, pollutants, dryness and dramatic changes in temperature throughout the day. Dewy, cashmere-soft and non-oily, this cream cushions skin and infuses moisture even in severe conditions, for a fulfilling skincare experience.**

• Formulated with SHISEIDO's ingredient Skingenecell Enmei(RF), the key to beautiful skin.

NON-COMEDOGENIC.
DERMATOLOGIST-TESTED.

* Can be generated in daily environments when exposed to UV rays.

** UV rays, pollutants, dryness and sudden changes in temperature and humidity.

Drug Facts (continued)

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:

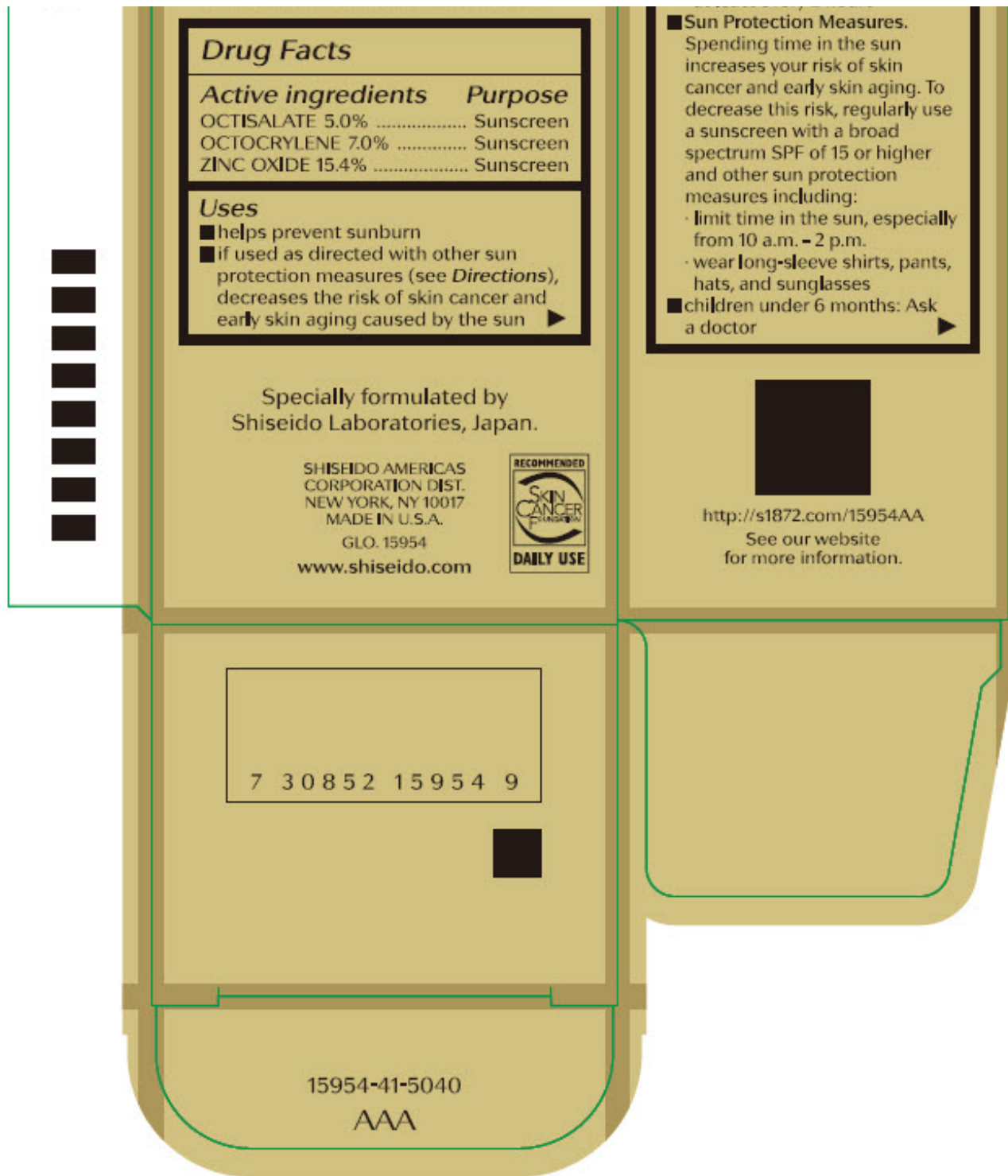
- after 40 minutes of swimming or sweating

- immediately after towel drying

- at least every 2 hours

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SHISEIDO FUTURE SOLUTION LX UNIVERSAL DEFENSE E

octisalate, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-482
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	2.523 g in 50 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	3.532 g in 50 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	7.723 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISODODECANE (UNII: A8289P68Y2)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
PRUNUS SPECIOSA LEAF (UNII: Q71D900FVU)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
RASPBERRY (UNII: 4N14V5R27W)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
PPG-17 (UNII: OV0Q322E0U)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
ISO STEARIC ACID (UNII: X33R8U0062)	
C30-45 ALKYL METHICONE (UNII: NFX970DSI2)	
C30-45 OLEFIN (UNII: 6DWD51M0O8)	
SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALCOHOL (UNII: 3K9958V90M)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
TALC (UNII: 7SEV7J4R1U)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	

ERGOTHIONEINE (UNII: BDZ3DQM98W)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-482-60	1 in 1 CARTON	01/01/2020	
1		50 mL in 1 TUBE; 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	01/01/2020	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICAS INC.		782677132	MANUFACTURE(58411-482) , ANALYSIS(58411-482)

Revised: 10/2019

SHISEIDO AMERICAS CORPORATION