SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR- octinoxate, octocrylene, and zinc oxide lotion SHISEIDO AMERICA INC.

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 UV PROTECTOR CREAM

Drug Facts

ACTIVE INGREDIENTS:	Purpose
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 12.5%	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
- 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, ISODODECANE, SD ALCOHOL 40-B, DIPROPYLENE GLYCOL,

ETHYLHEXYL PALMITATE, PEG-10 DIMETHICONE, GLYCERIN, POLYMETHYLSILSESQUIOXANE, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, XYLITOL, METHYL METHACRYLATE CROSSPOLYMER, THIOTAURINE, SCUTELLARIA BAICALENSIS ROOT EXTRACT, PAEONIA ALBIFLORA ROOT EXTRACT, ONONIS SPINOSA ROOT EXTRACT, ECTOIN, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, HYDROGEN DIMETHICONE, BUTYLENE GLYCOL, DISODIUM EDTA, DISTEARDIMONIUM HECTORITE, ALUMINA, BHT, TRIETHOXYCAPRYLYLSILANE, SYZYGIUM JAMBOS LEAF EXTRACT, TOCOPHEROL, PHENOXYETHANOL, BENZOIC ACID, FRAGRANCE, TITANIUM DIOXIDE, MICA,

Other information

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

Questions or comments?

Call toll free 1-800-906-7503
SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022
SHISEIDO DIST. NEW YORK • PARIS • MILANO

PRINCIPAL DISPLAY PANEL - 30mL Bottle Carton SHISEIDO

Anti-Aging UV Care

42

Urban Environment Oil-Free UV Protector BROAD SPECTRUM SPF 42 For Face

WATER RESISTANT (40 MINUTES)

SUNSCREEN

30mL 1 FL. OZ.

Urban Environment Oil-Free UV Protector BROAD SPECTRUM SPF 42 For Face

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Anti-Aging UV Care

42

Urban Environment Oil-Free UV Protector

> BROAD SPECTRUM SPF 42

> > For Face

WATER RESISTANT (40 MINUTES)

SUNSCREEN

30mL 1 FL. OZ.

Drug Facts (continued)

Inactive ingredients

WATER - DIMETHICONE - ISODODECANE SD ALCOHOL 40-8 - DIPROPYLENE GLYCOL ETHYLHEXYL PALMITIATE - PEG-10 DIMETHICONE GLYCERIN - POLYMETHYLSILSESOLIOXANE VINYL DIMETHICONE/METHICONE
SL.SESOLIOXANE CROSSPOLYMER POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER XYLITOL METHYL METHACRYLATE CROSSPOLYMER -

METHYL METHACKYLATE CHUSSPLLYMEN -THOTALIRNE -SOUTELLARIA BAKCALENSIS ROOT EXTRACT -

PAECINIA ALBIRLORA ROOT EXTRACT -Onomis servosa root extract - ectoin -Lauryl Peg-8 Polydimethylsiloxyethyl Dimethicome -

HYDROGEN CIMETHICONE • BUTYLENE GLYCOL • DISCOILM EDTA •

DISTEARDINOMUM HECTORITE - ALUMINA -BHT - TRIETHOXYCAPRYLYLSILANE -

SYZYGILM JAMBOS LEAF EXTRACT +

TOCOPHEROL • PHENOXYETHANOL •

BENZOIC ACID + FRAGRANCE +

TTANUM DICKIDE · MICA ·

Other Information

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Multi-Environment Defense. Comprehensive Skin Protection.

An ultra-light, oil-free, sun protection lotion for the face that controls excess sebum and gives skin a matte appearance while guarding against daily environmental aggressors. Promotes the natural beauty of skin by helping to prevent oxidation and the skin-damaging effects of sebum.

- ONON-COMEDOGENIC
- ODERMATOLOGIST AND OPHTHALMOLOGIST TESTED.

Drug Facts

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SHISEIDO AMERICA INC. NEW YORK, N.Y. 10022 MADE IN U.S.A. SHISEIDO DIST. NEW YORK-PARIS-MILANO GLO. 10512 www.shiseido.com

Drug Facts (continued)

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- Ask a doctor

Drug Facts (continued)

Questions or Comments? Call toll free 1-800-906-7503

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SHISEIDO URBAN ENVIRONMENT OIL-FREE UV PROTECTOR

octinoxate, octocrylene, and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-272
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1557 mg in 31.77 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	953 mg in 31.77 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	3971 mg in 31.77 g	

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
ISO DO DECANE (UNII: A8289 P68 Y2)	
DIPRO PYLENE GLYCOL (UNII: E107L85C40)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8 PR7V1SVM0)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
XYLITOL (UNII: VCQ006KQ1E)	
THIO TAURINE (UNII: NQZ2D7AO62)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ECTO INE (UNII: 7GXZ3858RY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
EDETATE DISO DIUM (UNII: 7FLD91C86K)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
TRIETHO XYCAPRYLYLSILANE (UNII: LDC331P08E)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENO XYETHANO L (UNII: HIE492ZZ3T)	
BENZOIC ACID (UNII: 8 SKN0 B0 MIM)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-272- 10	1 in 1 CARTON	10/01/2012	
1		31.77 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:52686-272- 80	2.12 g in 1 POUCH; Type 0: Not a Combination Product	10/01/2012	
3	NDC:52686-272- 11	1 in 1 CARTON	10/01/2012	
3		7.41 g 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	10/01/2012	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment			
Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-272), ANALYSIS(52686-272)

Revised: 12/2019 SHISEIDO AMERICA INC.