

**SHISEIDO SUN PROTECTION EYE- octinoxate, octocrylene, and zinc oxide cream**  
**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.*

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**SHISEIDO SUN PROTECTION EYE CREAM**

***Drug Facts***

<b>ACTIVE INGREDIENTS:</b>	<b>Purpose</b>
OCTINOXATE 2.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 10.6%	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 • ISOHEXADECANE • GLYCERIN • BUTYLENE GLYCOL • DIPROPYLENE GLYCOL • ISODODECANE • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • DISTEARDIMONIUM HECTORITE • POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER • TRIMETHYLSILOXYSILICATE • XYLITOL • METHYL GLUCETH-10 • DIMETHICONE • SD ALCOHOL 40-B • PEG/PPG-14/7 DIMETHYL ETHER • ZINC MYRISTATE • TOCOPHERYL

ACETATE • DIPOTASSIUM GLYCYRRHIZATE • SCUTELLARIA BAICALENSIS ROOT  
EXTRACT • ONONIS SPINOSA ROOT EXTRACT • ECTOIN • SOPHORA ANGUSTIFOLIA  
ROOT EXTRACT • HYDROGEN DIMETHICONE • ISOSTEARIC ACID • TRISODIUM EDTA •  
ALCOHOL • ALUMINA • TRIETHOXYCAPRYLYLSILANE • BHT • TOCOPHEROL • SYZYGIUM  
JAMBOS LEAF EXTRACT • PHENOXYETHANOL • FRAGRANCE • TITANIUM DIOXIDE •

**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 - 15mL Tube Carton**

**SHISEIDO**

Multi-Defense  
Sun Protection  
System

**34**

Sun Protection  
Eye Cream

BROAD SPECTRUM  
SPF 34

SUNSCREEN

15mL NET WT. .6 OZ.

37x26x100  
NS 1 2 3 4 5 6 7 8 9 0

SHISEIDO  
SUN PROTECTION EYE CREAM  
BROAD SPECTRUM  
SPF 34

**OUTPOWER THE SUN**

A rich eye-area cream that minimizes the appearance of wrinkles and enhances skin's radiance while providing effective protection against UVA/UVB rays.

- DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED.
- SPECIALLY FORMULATED BY SHISEIDO LABORATORIES, JAPAN.

**Drug Facts**

**Active ingredients Purpose**  
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 OCTOCRYLENE 3.0% ... Sunscreen  
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SHISEIDO AMERICA INC.  
 NEW YORK, N.Y. 10022  
 MADE IN U.S.A.  
 SHISEIDO DIST. NEW YORK-PARIS-MILANO  
 GLO. 10478  
[www.shiseido.com](http://www.shiseido.com)

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**Drug Facts (continued)**

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Sun Protection  
Eye Cream  
BROAD SPECTRUM  
SPF 34

SHISEIDO

Multi-Defense  
Sun Protection  
System

34

Sun Protection  
Eye Cream  
BROAD SPECTRUM  
SPF 34  
SUNSCREEN

15mL NET WT. .6 OZ.

**Drug Facts (continued)**

**Inactive ingredients**

WATER - ISOHEXADECANE - GLYCERIN - BUTYLENE GLYCOL - PROPYLENE GLYCOL - ISODODECANE - LAURYL PEG-8 - POLYDIMETHYLSILOXYMETHYL DIMETHICONE - DISTEARDINONIUM HECTORITE - POLYBUTYLENE GLYCOL/PPG-8/1 COPOLYMER - TRIMETHYLSILOXYLICATE - XYLITOL - METHYL GLUCETH-10 - DIMETHICONE - SD ALCOHOL 40-8 - PEG/PPG-14/7 DIMETHYL ETHER - ZINC MYRISTATE - TOCOPHERYL ACETATE - DIPOTASSIUM GLYCYPHOSPHATE - SCUTELLARIA BAICALENSIS ROOT EXTRACT - ONONIS SPINOSA ROOT EXTRACT - ECTOIN - SOPHORA ANGUSTIFOLIA ROOT EXTRACT - HYDROGEN DIMETHICONE - ISOSTEARIC ACID - TRISODIUM EDTA - ALCOHOL - ALUMINA - TRIMETHOXYCAPRYLYLSILANE - BHT - TOCOPHEROL - SYZIGIUM JAMBOS LEAF EXTRACT - PHENOXYETHANOL - FRAGRANCE - TITANIUM DIOXIDE

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# SHISEIDO SUN PROTECTION EYE

octinoxate, octocrylene, and zinc oxide cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-335
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	479 mg in 16.5 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	495 mg in 16.5 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	1749 mg in 16.5 g

## Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X10UF1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ISODODECANE (UNII: A8289P68Y2)	
TRIMETHYLSILOXYLICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
XYLITOL (UNII: VCQ006KQ1E)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
ZINC MYRISTATE (UNII: K09A9E2GGO)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ECTOINE (UNII: 7GXZ3858RY)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
ISO STEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
ALCOHOL (UNII: 3K9958V90M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-335-60	1 in 1 CARTON		
1		16.5 g in 1 TUBE		
2	NDC:52686-335-61	1 in 1 CARTON		
2	NDC:52686-335-80	1.65 g in 1 POUCH		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	12/01/2012	

**Labeler** - SHISEIDO AMERICA INC. (782677132)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-335) , ANALYSIS(52686-335)

### Establishment

Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(52686-335)

Revised: 2/2013

SHISEIDO AMERICA INC.