

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

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**SHISEIDO SUN PROTECTION EYE CREAM**

***Drug Facts***

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**ACTIVE INGREDIENTS: Purpose**

OCTINOXATE 2.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 10.6%	Sunscreen

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**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 • SYZYGIIUM 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**

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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)

**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 -  
 TRIMETHYLSILOXYMETHYL  
 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 -  
 TRIMETHOXYCARYLYLSILANE - BHT -  
 TOCOPHEROL -  
 SYZIGIUM JAMBOS LEAF EXTRACT -  
 PHENOXYETHANOL - FRAGRANCE -  
 TITANIUM DIOXIDE -

**Other Information**

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**Questions or Comments?**

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12516-41-5041

AAA

# SHISEIDO SUN PROTECTION EYE

octinoxate, octocrylene, and zinc oxide cream

## Product Information

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

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	
<b>METHYL GLUCETH-10</b> (UNII: N0MWT4C7WH)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG/PPG-14/7 DIMETHYL ETHER</b> (UNII: 6DNW9T7YT2)	
<b>ZINC MYRISTATE</b> (UNII: K09A9E2GGO)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)	
<b>SCUTELLARIA BAICALENSIS ROOT</b> (UNII: 7J95K7ID2S)	
<b>ONONIS SPINOSA ROOT</b> (UNII: FD2FMC53M1)	
<b>ECTOINE</b> (UNII: 7GXZ3858RY)	
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K)	
<b>ISOSTEARIC ACID</b> (UNII: X33R8U0062)	
<b>EDETATE TRISODIUM</b> (UNII: 420IP921MB)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>SYZYGIUM JAMBOS LEAF</b> (UNII: 407Z4W5LFF)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-335-60	1 in 1 CARTON	12/01/2012	11/01/2015
1		16.5 g 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 drug	M020	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)

Revised: 12/2023

SHISEIDO AMERICA INC.