SHISEIDO SUN PROTECTION EYE- octinoxate, 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 SUN PROTECTION EYE CREAM

Drug Facts

ACTIVE INGREDIENTS:	Purpose
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 - 15 mL Tube Carton

SHISEIDO
GINZA TOKYO

Sun Protection
Eye Cream

34

BROAD SPECTRUM
SPF 34

SUNSCREEN

15mL NET WT. .6 OZ.

SHISEIDO SUN PROTECTION EYE

octinoxate, octocrylene, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58411-345
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: 918X1OUF1E)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
ISODODECANE (UNII: A8289P68Y2)	
TRIMETHYLSILOXYSILICATE (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 DIPOTASSIUM (UNII: CA2Y0FE3FX)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ECTOINE (UNII: 7GXZ3858RY)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
ALCOHOL (UNII: 3K9958V90M)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
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:58411-345-60	1 in 1 CARTON	12/01/2012	
1		16.5 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:58411-345-61	1 in 1 CARTON	12/01/2012	
2	NDC:58411-345-80	1.65 g in 1 POUCH; 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	12/01/2012	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-345) , ANALYSIS(58411-345)

Revised: 12/2019 SHISEIDO AMERICAS CORPORATION