

CLE DE PEAU BEAUTE UV PROTECTIVE- 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.

CLÉ DE PEAU BEAUTÉ UV PROTECTIVE

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
ZINC OXIDE 16.4%	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.

Directions

- 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•DIPROPYLENE GLYCOL•ISOHEXADECANE•ISOPROPYL MYRISTATE•GLYCERIN•SD ALCOHOL 40-B•LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE•DIMETHICONE•POLYMETHYL METHACRYLATE•DISTEARDIMONIUM HECTORITE•POLYMETHYLSILSESQUIOXANE•PEG/PPG-14/7 DIMETHYL ETHER•POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER•MACADAMIA SEED OIL POLYGLYCERYL-6 ESTERS BEHENATE•PEG-6•PEG-32•SILICA•TREHALOSE•TOCOPHERYL ACETATE•POLYQUATERNIUM-51•SODIUM ACETYLATED HYALURONATE•DIPOTASSIUM GLYCYRRHIZATE•SAXIFRAGA SARMENTOSA EXTRACT•GINKGO BILOBA LEAF EXTRACT•THYMUS SERPILLUM EXTRACT•CRATAEGUS MONOGYNA FLOWER EXTRACT•HYDROLYZED SILK•2-O-ETHYL ASCORBIC ACID•SCUTELLARIA BAICALENSIS ROOT EXTRACT•UNCARIA GAMBIR EXTRACT•GARCINIA MANGOSTANA BARK EXTRACT•HIBISCUS SABDARIFFA FLOWER EXTRACT•PANAX GINSENG ROOT EXTRACT•BUPLEURUM FALCATUM ROOT EXTRACT•HYDROLYZED CONCHIOLIN PROTEIN•HYDROGENATED POLYDECENE•HYDROGEN DIMETHICONE•ISOSTEARIC ACID•BUTYLENE GLYCOL•TRISODIUM EDTA•TALC•ALCOHOL•BHT•TOCOPHEROL•TRIETHOXYCAPRYL SILANE•THEANINE•PHENOXYETHANOL•FRAGRANCE•IRON OXIDES•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

PRINCIPAL DISPLAY PANEL - 50 mL Tube Carton

clé de peau
BEAUTÉ

50+

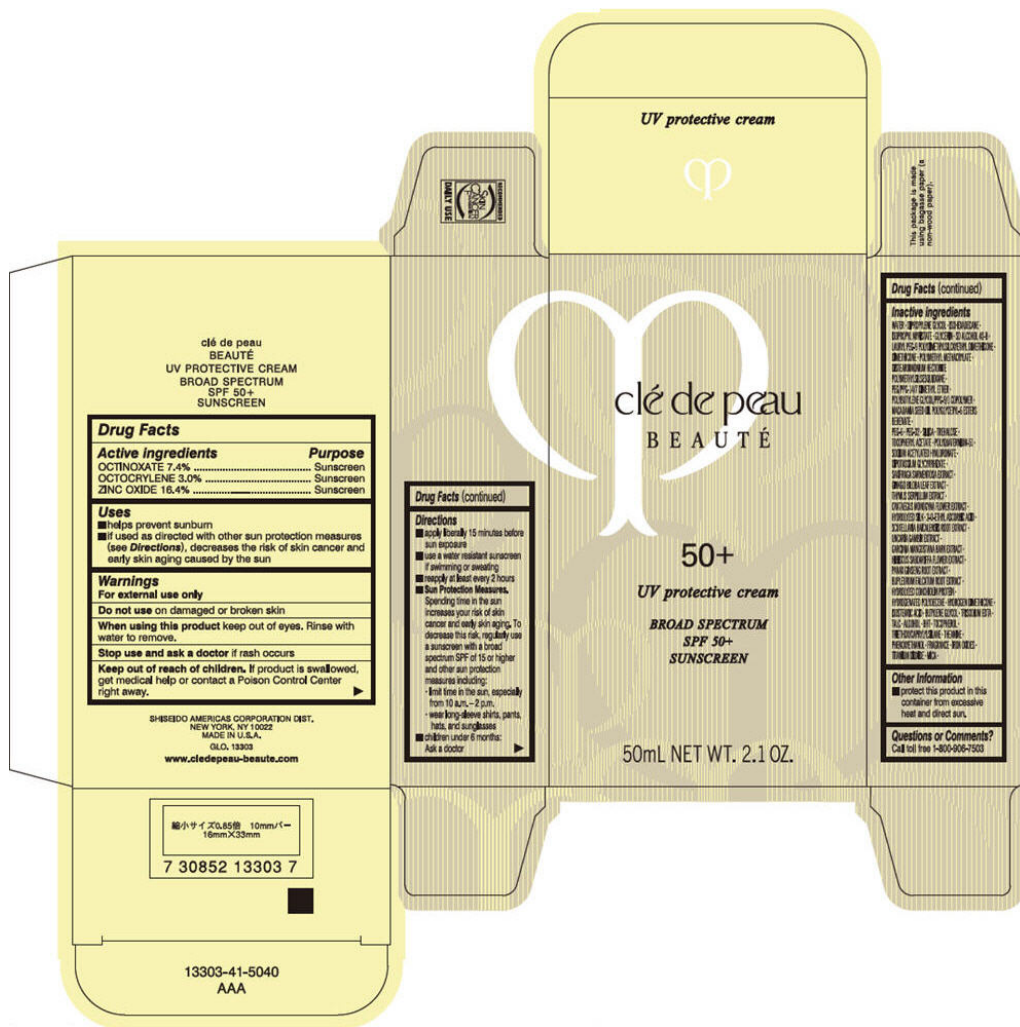
UV protective cream

BROAD SPECTRUM

SPF 50+

SUNSCREEN

50mL NET WT. 2.1 OZ.



CLE DE PEAU BEAUTE UV PROTECTIVE			
octinoxate, octocrylene, and zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-29 1
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	3870 mg in 50 mL	
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	1569 mg in 50 mL	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	8577 mg in 50 mL	
Inactive Ingredients			
Ingredient Name	Strength		

ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)
GLYCERIN (UNII: PDC6A3C0OX)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
TREHALOSE (UNII: B8WCK70T7I)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WP7EW8)
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
GINKGO (UNII: 19FUJ2C58T)
THYMUS SERPYLLUM (UNII: 86H4S6K51N)
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)
2-O-ETHYL ASCORBIC ACID (UNII: 801MI4RK9K)
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)
HIBISCUS SABDARIFFA FLOWER (UNII: 45TGG6IU6M)
ASIAN GINSENG (UNII: CUQ3A77YXI)
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)
HYDROGENATED POLYDECENE (550 MW) (UNII: U333R16EB7)
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)
ISOSTEARIC ACID (UNII: X33R8U0062)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
EDETATE TRISODIUM (UNII: 420IP921MB)
TALC (UNII: 7SEV7J4R1U)
ALCOHOL (UNII: 3K9958V90M)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
THEANINE (UNII: 8021PR16QO)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MICA (UNII: V8A1AW0880)
WATER (UNII: 059QF0K00R)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
ISOHEXADECANE (UNII: 918X1OUF1E)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-291-60	1 in 1 CARTON	02/01/2017	
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 not final	part352	02/01/2017		

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment				
Name	Address	ID/FEI	Business Operations	
SHISEIDO AMERICA INC.		782677132	manufacture(58411-291) , analysis(58411-291)	