

**CLE DE PEAU BEAUTE UV PROTECTION- octinoxate, octocrylene, oxybenzone, 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.

**CLE DE PEAU BEAUTE UV PROTECTION
CREAM**

Drug Facts

Active ingredients

OCTINOXATE 7.4%
OCTOCRYLENE 3.0%
OXYBENZONE 1.5%
ZINC OXIDE 9.0%

Purpose

Sunscreen
Sunscreen
Sunscreen
Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply evenly before sun exposure and as needed.
- children under 6 months of age: ask a doctor.

Inactive Ingredients

WATER • BUTYLENE GLYCOL • ISOHEXADECANE • DIMETHICONE • ISOPROPYL MYRISTATE • GLYCERIN • POLYMETHYLSILSESQUIOXANE • SD ALCOHOL 40-B • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • DISTEARDIMONIUM HECTORITE • POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER • PEG-6 • XYLITOL • PEG-32 • SODIUM HYALURONATE • TOCOPHERYL ACETATE • LACTOBACILLUS/HIBISCUS SABDARIFFA FLOWER FERMENT FILTRATE • CRATAEGUS MONOGYNA FLOWER EXTRACT • THIOTAURINE • DIPOTASSIUM GLYCYRRHIZATE • 2-O-ETHYL ASCORBIC ACID • SODIUM ACETYLATED HYALURONATE • POLYQUATERNIUM-51 • SAXIFRAGA SARMENTOSA EXTRACT • UNCARIA GAMBIR EXTRACT • GINKGO BILOBA LEAF EXTRACT • THYMUS SERPILLUM EXTRACT • ROSA ROXBURGHII FRUIT EXTRACT • HYDROLYZED

CONCHIOLIN PROTEIN • CURCUMA LONGA (TURMERIC) ROOT EXTRACT • HYPERICUM
ERECTUM EXTRACT • HYDROLYZED SILK • BUPLEURUM FALCATUM ROOT EXTRACT •
HYDROGENATED POLYDECENE • SILICA • ISOSTEARIC ACID • HYDROGEN DIMETHICONE
• TRISODIUM EDTA • BHT • ALCOHOL • TOCOPHEROL • PHENOXYETHANOL •
FRAGRANCE • TITANIUM DIOXIDE • MICA •

Questions?

1-800-906-7503

PRINCIPAL DISPLAY PANEL - 50 mL Carton

clé de peau

BEAUTÉ

SPF

50

PA+++

sunscreen

UV protection cream

50mL NET WT. 1.9 OZ.

UV protection cream



clé de peau
BEAUTÉ

SPF
50
PA+++
sunscreen

UV protection cream

50mL NET WT. 1.9 OZ.

Drug Facts
(continued)

Inactive ingredients

WATER • BUTYLENE GLYCOL • ISOHEXANE • DIMETHICONE •
DIPROPYL HYDROXYLATE • GLYCERIN •
POLYETHYLENE GLYCOLSULFONATE • SD ALCOHOL 40-8 •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE •
DIPROPYL ACRYLAMIDE •
POLYBUTYLENE GLYCOL PPG-11 COPOLYMER • PEG-6 •
XYLITOL • PEG-30 • SODIUM HYALURONATE •
TOCOPHERYL ACETATE •
LACTOBACILLUS FERMENTIS SIBIRIANICA FLOWER
FERMENT EXTRACT •
CRATAEGUS MONOCOMA FLOWER EXTRACT • THYMUS
SERPYLLIDAE EXTRACT • 2-(4-CIYLOXYPHENYL) ACID •
SODIUM ACETYLATED HYALURONATE • POLYGLUTAMINE •
SANTALUM ALBUM EXTRACT •
UNICHA SERRIFOLIUM EXTRACT • SINGAPOREAN LEMON EXTRACT •
THYMUS SERPYLLIDAE EXTRACT •
ROSA ROBURIFOLIA FRUIT EXTRACT •
HYDROLYZED CONDENSING PROTEIN •
CURCUMA LONGA (TURMERIC) ROOT EXTRACT •
IPERIZUM CRISTATUM EXTRACT • HYDROLYZED DNA •
BUPLEBIUM FULCUM ROOT EXTRACT •
HYDROGENATED POLYDECENE • SODIUM BOSTERANE ACID •
HYDROXYETHYLCELLULOSE • TRISODIUM EDTA • BUTYL ALCOHOL •
TOCOPHEROL • PHENYLETHANOL • FRAGRANCE •
TITANIUM DIOXIDE • MICA

Questions?
1-800-906-7503

64X32X108 1 2 3 4 5 6 7 8 9 0

clé de peau
BEAUTÉ
UV PROTECTION CREAM

READ INSERTION.

SHISEIDO AMERICA INC.
NEW YORK, N.Y. 10022
MADE IN U.S.A.

GLO, 31691

www.cledepeau-beaute.com

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%.....	Sunscreen
OCTOCRYLENE 3.0%.....	Sunscreen
OXYBENZONE 1.5%.....	Sunscreen
ZINC OXIDE 9.0%.....	Sunscreen

Uses

- helps prevent sunburn
- higher SPF gives more sunburn protection

Warnings

For external use only

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.

Drug Facts
(continued)

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply evenly before sun exposure and as needed.
- children under 6 months of age: ask a doctor.



This package is made using bagasse paper (a non-wood paper).

縮小サイズ0.85倍 10mmパター
16mm×33mm

7 30852 31691 X

31691-41-5040
AAA

CLE DE PEAU BEAUTE UV PROTECTION

octinoxate, octocrylene, oxybenzone, and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-259
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	4.06 g in 54.91 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	1.65 g in 54.91 g
Oxybenzone (UNII: 95OOS7VE0Y) (Oxybenzone - UNII:95OOS7VE0Y)	Oxybenzone	0.82 g in 54.91 g
Zinc oxide (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	4.94 g in 54.91 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
THIO TAURINE (UNII: NQZ2D7AO62)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
GINKGO (UNII: 19FUJ2C58T)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
TURMERIC (UNII: 856YO1Z64F)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-259-60	1 in 1 CARTON		
1		54.91 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	03/01/2012	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment			
Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-259) , ANALYSIS(52686-259)

Establishment			
Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(52686-259)

Revised: 2/2012

SHISEIDO AMERICA INC.