

**CLE DE PEAU BEAUTE UV PROTECTIVE VERY HIGH PROTECTION FOR BODY-
octinoxate, octocrylene, titanium dioxide, and zinc oxide emulsion
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 VERY HIGH PROTECTION FOR BODY

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
TITANIUM DIOXIDE 1.5%	Sunscreen
ZINC OXIDE 19.3%	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.

Flammable

Do not use near heat, flame, or while smoking

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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

DIMETHICONE•WATER•BUTYLENE GLYCOL•ISOPROPYL MYRISTATE•SD ALCOHOL 40-B•ISODODECANE•PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE•TRIMETHYLSILOXYSILICATE•GLYCERIN•PEG/PPG-14/7 DIMETHYL
ETHER•POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER•TREHALOSE•DEXTRIN
PALMITATE•TOCOPHERYL ACETATE•POLYQUATERNIUM-51•SODIUM ACETYLATED
HYALURONATE•DIPOTASSIUM GLYCYRRHIZATE•SAXIFRAGA SARMENTOSA
EXTRACT•GINKGO BILOBA LEAF EXTRACT•THYMUS SERPILLUM
EXTRACT•HYDROLYZED SILK•SCUTELLARIA BAICALENSIS ROOT EXTRACT•UNCARIA
GAMBIR EXTRACT•GARCINIA MANGOSTANA BARK EXTRACT•HIBISCUS SABDARIFFA
FLOWER EXTRACT•PANAX GINSENG ROOT EXTRACT•HYDROLYZED CONCHIOLIN
PROTEIN•HYDROGEN DIMETHICONE•ISOSTEARIC ACID•DISTEARDIMONIUM
HECTORITE•TALC•HYDRATED
SILICA•TRIETHOXYCAPRYLYLSILANE•ALCOHOL•TRISODIUM EDTA•CALCIUM
STEARATE•DISTEARYLDIMONIUM CHLORIDE•STEARIC
ACID•BHT•SILICA•THEANINE•METHYLPARABEN•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 - 75 mL Bottle Carton

clé de peau

BEAUTÉ

50+

WATER RESISTANT (80 MINUTES)

UV protective emulsion

very high protection

for body

BROAD SPECTRUM

SPF 50+

SUNSCREEN

75mL 2.5 FL. OZ.

*UV protective emulsion
very high protection for body*



clé de peau
BEAUTÉ

50+

WATER RESISTANT (80 MINUTES)

*UV protective emulsion
very high protection
for body*

**BROAD SPECTRUM
SPF 50+
SUNSCREEN**

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

Drug Facts (continued)

Inactive ingredients

DIMETHICONE · WATER · BUTYLENE GLYCOL ·
ISOPROPYL MYRISTATE · SD ALCOHOL 40-B ·
ISODODECANE ·
PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE ·
TRIMETHYLSILOXYSILICATE · GLYCERIN ·
PEG/PPG-14/7 DIMETHYL ETHER ·
POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER ·
TREHALOSE · DEXTRIN PALMITATE ·
TOCOPHERYL ACETATE · POLYQUATERNIUM-51 ·
SODIUM ACETYLATED HYALURONATE ·
DIPOTASSIUM GLYCYRRHIZATE ·
SAXIFRAGA SARMENTOSA EXTRACT ·
GINKGO BILOBA LEAF EXTRACT ·
THYMUS SERPILLUM EXTRACT ·
HYDROLYZED SILK ·
SCUTELLARIA BAICALENSIS ROOT EXTRACT ·
UNCARIA GAMBIR EXTRACT ·
GARCINIA MANGOSTANA BARK EXTRACT ·
HIBISCUS SABDARIFFA FLOWER EXTRACT ·
PANAX GINSENG ROOT EXTRACT ·
HYDROLYZED CONCHILIN PROTEIN ·
HYDROGEN DIMETHICONE · ISOSTEARIC ACID ·
DISTEARDIMONIUM HECTORITE · TALC ·
HYDRATED SILICA · TRIETHOXYCAPRYLYLSILANE ·
ALCOHOL · TRISODIUM EDTA ·
CALCIUM STEARATE ·
DISTEARYLDIMONIUM CHLORIDE · STEARIC ACID ·
BHT · SILICA · THEANINE · METHYLPARABEN ·
PHENOXYETHANOL · FRAGRANCE · IRON OXIDES ·
TITANIUM DIOXIDE · MICA ·

Other Information

■ protect this product in this

75mL 2.5 FL. OZ.

container from excessive heat and direct sun.

Questions or Comments?
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clé de peau
BEAUTÉ
UV PROTECTIVE EMULSION
VERY HIGH PROTECTION FOR BODY
BROAD SPECTRUM
SPF 50+
SUNSCREEN

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Drug Facts (continued)

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Uses

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SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 13301

www.cledepeau-beaute.com

縮小サイズ0.85倍 10mmバー
16mm×33mm

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13301-41-5040
AAA

before sun exposure

- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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:
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-289
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	5678 mg in 75 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2302 mg in 75 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1151 mg in 75 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14808 mg in 75 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
TREHALOSE (UNII: B8WCK70T7I)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
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)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)	
HIBISCUS SABDARIFFA FLOWER (UNII: 45TGG6IU6M)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
ISO STEARIC ACID (UNII: X33R8U0062)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TALC (UNII: 7SEV7J4R1U)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
ALCOHOL (UNII: 3K9958V90M)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
CALCIUM STEARATE (UNII: 776XM7047L)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THEANINE (UNII: 8021PR16QO)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-289-10	1 in 1 CARTON	02/01/2017	
1		75 mL in 1 BOTTLE; 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(58411-289) , analysis(58411-289)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION