

**CLE DE PEAU BEAUTE UV PROTECTIVE FOR BODY N- ensulizole, octisalate, octocrylene, 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 EMULSION FOR BODY n

Drug Facts

Active ingredients	Purpose
ENSULIZOLE 2.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 5.0%	Sunscreen
ZINC OXIDE 19.4%	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.

Flammable: Do not use near heat, flame, or while smoking.

Directions

For sunscreen use:

- 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

WATER • DIMETHICONE • DIISOPROPYL SEBACATE • GLYCERIN • ALCOHOL DENAT. • TRISILOXANE • PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • SILICA • ISOPROPYL MYRISTATE • DIPHENYLSILOXY PHENYL TRIMETHICONE • ISODODECANE • TRIMETHYLSILOXYSILICATE • TRIETHANOLAM IN E • DEXTRIN PALMITATE • TREHALOSE • MENTHA PIPERITA (PEPPERMINT) LEAF EXTRACT • RUBUS SUAVISSIMUS (RASPBERRY) LEAF EXTRACT • GLYCINE • PEG/PPG-14/7 DIMETHYL ETHER • HYDRANGEA SERRATA LEAF EXTRACT • THYMUS SERPYLLUM EXTRACT • SODIUM ACETYLATED HYALURONATE • AMINOETHANESULFINIC ACID • SODIUM HYALURONATE • TOCOPHERYL ACETATE-ANGELICA ACUTILOBA ROOT EXTRACT • HYDROLYZED CONCHIOLIN PROTEIN • HYDROLYZED SILK • PERILLA OCYMOIDES LEAF EXTRACT • POLYQUATERNIUM-51 • PANAX GINSENG ROOT EXTRACT • SAXIFRAGA SARMENTOSA EXTRACT • GINKGO BILOBA LEAF EXTRACT-SCUTELLARIA BAICALENSIS ROOT EXTRACT • GARCINIA MANGOSTANA BARK EXTRACT • DISTEARDIMONIUM HECTORITE • HYDROGEN DIMETHICONE • ISOSTEARIC ACID • BUTYLENE GLYCOL • DISODIUM EDTA • SORBITAN SESQUIISOSTEARATE • ALCOHOL • TOCOPHEROL • BHT • SODIUM METABISULFITE • SYNTHETIC FLUORPHLOGOPITE • THEANINE • SYZYGIIUM JAMBOS LEAF EXTRACT • PHENOXYETHANOL • FRAGRANCE • RED 33 • YELLOW 5 • YELLOW 6

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 - 100 mL Container Carton

clé de peau
BEAUTÉ

UV PROTECTIVE EMULSION
FOR BODY n

60+
BROAD SPECTRUM
SPF 60+
WATER RESISTANT
(80 MINUTES)
SUNSCREEN

100mL 3.3 FL. OZ.



CLÉ DE PEAU
BEAUTÉ
UV PROTECTIVE EMULSION FOR BODY N
BROAD SPECTRUM SPF 60+
SUNSCREEN

For skin with a radiance that evolves day by day. A sunscreen for body utilizing **Adaptable Innershield Technology** supports skin's natural protective abilities. Powerfully defends against the sun's damaging rays and selectively allows the latent benefits of red light in sunlight to pass through to the skin. With continued use, improves a lack of moisture in the skin while also boosting skin's firmness and smoothness for a more radiantly youthful look.

- Formulated with **Skin-Empowering Illuminator**, our exclusive skincare ingredient.
- DERMATOLOGIST-TESTED.

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SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
www.cledepeau-beaute.com

總小サイズ0.85倍 10mm/←
16mm×33mm

7 30852 21118 6

2次元
コード

21118-41-5040
AAA

UV PROTECTIVE EMULSION FOR BODY n



clé de peau
BEAUTÉ

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BROAD SPECTRUM
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Drug Facts
(continued)

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Drug Facts
(continued)

Inactive Ingredients

TOCOPHERYL ACETATE-ANGELICA ACUTILOBA ROOT EXTRACT-HYDROLYZED CONCHOLIN PROTEIN-HYDROLYZED SILK-PERILLA OCYMOIDES LEAF EXTRACT-POLYQUATERNIUM-51-PANAX GINSENG ROOT EXTRACT-SAXIFRAGA SARMENTOSA EXTRACT-GINKGO BILOBA LEAF EXTRACT-SCUTELLARIA BAIJALENSIS ROOT EXTRACT-GARCINIA MANGOSTANA BARK EXTRACT-DISTEARDIMONIUM HECTORITE-HYDROGEN DIMETHICONE-ISOSTEARIC ACID-BUTYLENE GLYCOL-DISODIUM EDTA-SORBITAN SESQUISOSEARATE-ALCOHOL-TOCOPHEROL-BHT-SODIUM METABISULFITE-SYNTHETIC FLUORPHLOGOPITE-THEANINE-SYZYGIUM JAMBOS LEAF EXTRACT-PHENOXYETHANOL-FRAGRANCE-RED 33-YELLOW 5-YELLOW 6-

Other Information

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Questions or Comments?

Call toll free
1-800-906-7503

<MI11908-81>



QRコード

http://cpt1982.com/21118CP
See our website for more information.

CLE DE PEAU BEAUTE UV PROTECTIVE FOR BODY N

ensulizole, octisalate, octocrylene, and zinc oxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-858
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	2.384 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.96 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5.96 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	23.1248 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPOTAURINE (UNII: 5L08GE4332)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCINE (UNII: TE7660XO1C)	
HYDRANGEA SERRATA LEAF (UNII: 2SFZ1X3QA9)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
THEANINE (UNII: 8021PR16QO)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2YOI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SORBITAN SESQUIISOSTEARATE (UNII: VU97D01BF9)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
TROLAMINE (UNII: 9O3K93S3TK)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ISODODECANE (UNII: A8289P68Y2)	

DEXTRIN PALMITATE (CORN; 20000 MW) (UNII: 89B2BSF9I3)
TRISILOXANE (UNII: 9G1ZW13R0G)
ALCOHOL (UNII: 3K9958V90M)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
TREHALOSE (UNII: B8WCK70T7I)
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)
DIMETHICONE (UNII: 92RU3N3Y1O)
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)
GINKGO (UNII: 19FUJ2C58T)
MENTHA PIPERITA LEAF (UNII: A389O33LX6)
ASIAN GINSENG (UNII: CUQ3A77YXI)
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)
EDETATE DISODIUM (UNII: 7FLD91C86K)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
THYMUS SERPYLLUM WHOLE (UNII: 86H4S6K51N)
RUBUS CHINGII VAR. SUAVISSIMUS LEAF (UNII: U5KPW4NCFM)
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-858-40	1 in 1 CARTON	01/01/2024	
1		100 mL in 1 CONTAINER; 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	01/01/2024	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 5/2023

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