

**CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N- avobenzone, octinoxate, octocrylene, and oxybenzone 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 PROTECTIVE FORTIFYING CREAM n

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.0%	Sunscreen
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 5.0%	Sunscreen
OXYBENZONE 2.0%	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•CYCLOPENTASILOXANE•GLYCERIN•DIISOPROPYL SEBACATE•BUTYLENE GLYCOL•DIETHYLHEXYL SUCCINATE•SD ALCOHOL 40-B•TREHALOSE•PEG/PPG-14/7 DIMETHYL ETHER•DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER•TOCOPHERYL

ACETATE•PEG/PPG-17/4 DIMETHYL ETHER•PHYTOSTERYL
MACADAMATE•POLYQUATERNIUM-51•GINKGO BILOBA LEAF EXTRACT•ANGELICA
ACUTILOBA ROOT EXTRACT•PAEONIA ALBIFLORA ROOT EXTRACT•CRATAEGUS
MONOGYNA FLOWER EXTRACT•PANAX GINSENG ROOT EXTRACT•GLYCINE•ONONIS
SPINOSA ROOT EXTRACT•HYDROLYZED SILK•ROSA CANINA FRUIT
EXTRACT•ZANTHOXYLUM PIPERITUM PEEL EXTRACT•HIBISCUS ESCULENTUS FRUIT
EXTRACT•FAGUS SYLVATICA BUD EXTRACT•SODIUM ACETYLATED
HYALURONATE•PERILLA OCYMOIDES LEAF EXTRACT•ROSA ROXBURGHII FRUIT
EXTRACT•HYDROLYZED CONCHIOLIN PROTEIN•ISODONIS JAPONICUS LEAF/STALK
EXTRACT•BUPLEURUM FALCATUM ROOT EXTRACT•BEHENETH-20•PPG-17•BEHENYL
ALCOHOL•CARBOMER•POLYSORBATE 20•TRIETHANOLAMINE•DISODIUM
EDTA•STEARYL ALCOHOL•HYDROXYPROPYL METHYLCELLULOSE STEAROXY
ETHER•THEANINE•SODIUM CITRATE•ALCOHOL•SODIUM METAPHOSPHATE•CITRIC
ACID•BHT•TOCOPHEROL•PHENOXYETHANOL•METHYLPARABEN•BENZOIC
ACID•FRAGRANCE•MICA•TITANIUM DIOXIDE•IRON OXIDES•

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 - 12 mL Bottle Carton

clé de peau
BEAUTÉ

PROTECTIVE FORTIFYING CREAM n
BROAD SPECTRUM
SPF 22
SUNSCREEN

12mL NET WT. .43 OZ.

PROTECTIVE FORTIFYING CREAM n



clé de peau
BEAUTÉ

PROTECTIVE FORTIFYING CREAM n
BROAD SPECTRUM
SPF 22
SUNSCREEN

12mL NET WT. .43 OZ.

Drug Facts (continued)

Inactive ingredients

WATER • CYCLOPENTASILOXANE • GLYCERIN • DIISOPROPYL SEBACATE • BUTYLENE GLYCOL • DIETHYLHEXYL SUCCINATE • SD ALCOHOL 40-B • TREHALOSE • PEG/PPG-14/7 DIMETHYL ETHER • DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER • TOCOPHERYL ACETATE • PEG/PPG-17/4 DIMETHYL ETHER • PHYTOSTERYL MACADAMIATE • POLYQUATERNIUM-51 • GINKGO BILOBA LEAF EXTRACT • ANGELICA ACUTILOBA ROOT EXTRACT • PAEONIA ALBIFLORA ROOT EXTRACT • CRATAEGUS MONOGYNA FLOWER EXTRACT • PANAX GINSENG ROOT EXTRACT • GLYCINE • ONONIS SPINOSA ROOT EXTRACT • HYDROLYZED SILK • ROSA CANINA FRUIT EXTRACT • ZANTHOXYLUM PIPERITUM PEEL EXTRACT • HIBISCUS ESCULENTUS FRUIT EXTRACT • FAGUS SYLVATICA BUD EXTRACT • SODIUM ACETYLATED HYALURONATE • PERILLA OCYMOIDES LEAF EXTRACT • ROSA ROXBURGHII FRUIT EXTRACT • HYDROLYZED CONCHIOLIN PROTEIN • ISODONIS JAPONICUS LEAF/STALK EXTRACT • BUPLEURUM FALCATUM ROOT EXTRACT • BEHENETH-20 • PPG-17 • BEHENYL ALCOHOL • CARBOMER • POLYSORBATE 20 • TRIETHANOLAMINE • DISODIUM EDTA • STEARYL ALCOHOL • HYDROXYPROPYL METHYLCELLULOSE STEAROXY ETHER • THEANINE • SODIUM CITRATE • ALCOHOL • SODIUM METAPHOSPHATE • CITRIC ACID • BHT • TOCOPHEROL • PHENOXYETHANOL • METHYLPARABEN • BENZOIC ACID • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES



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PROTECTIVE FORTIFYING CREAM n

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SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
Q.L.O. 16333
www.cledepeaubaute.com

Drug Facts (continued)

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QRコード

<http://cpb1982.com/I6333CP>
See our website for more information.

Drug Facts (continued)

Other Information

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Questions or Comments?

Call toll free 1-800-906-7503

Reducing the quantity of application will lower the level of sunscreen protection significantly.

縮小サイズ0.85倍 10mmバー
16mm×33mm

2次元
コード



7 30852 16333 1

16333-41-5040
AAA

CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N

avobenzone, octinoxate, octocrylene, and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-562
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.2472 g in 12 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	0.60564 g in 12 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.618 g in 12 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.2472 g in 12 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
TREHALOSE (UNII: B8WCK70T7I)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
GINKGO (UNII: 19FUJ2C58T)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
GLYCINE (UNII: TE7660XO1C)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
ZANTHOXYLUM PIPERITUM FRUIT RIND (UNII: 728JDI7G4M)	
FAGUS SYLVATICA FLOWER BUD (UNII: 6D5V13045W)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
PPG-17 (UNII: OV0Q322E0U)	
DOCOSANOL (UNII: 9G1OE216XY)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARYL ALCOHOL (UNII: 2KR8914H1Y)	

THEANINE (UNII: 8021PR16QO)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
ALCOHOL (UNII: 3K9958V90M)
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
METHYL PARABEN (UNII: A2I8C7HI9T)
BENZOIC ACID (UNII: 8SKN0B0MIM)
MICA (UNII: V8A1AW0880)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-562-10	1 in 1 CARTON	03/01/2020	
1		12 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 final	part352	03/01/2020	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 4/2020

SHISEIDO AMERICAS CORPORATION