

**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 EMULSION n

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 2.0%	Sunscreen
OXYBENZONE 1.0%	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 • DIPROPYLENE GLYCOL • SD ALCOHOL 40-B • GLYCERIN • HYDROGENATED POLYDECENE • XYLITOL • DIMETHICONE • ISODODECANE • PEG/PPG-14/7 DIMETHYL ETHER • PEG-5 GLYCERYL STEARATE • SILICA • ISOSTEARIC ACID • DIPHENYLSILOXY

PHENYL TRIMETHICONE • XANTHAN GUM • TREHALOSE • TOCOPHERYL ACETATE • PEG/PPG-17/4 DIMETHYL ETHER • PHYTOSTERYL MACADAMIATE • 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 • PPG-17 • TRIETHANOLAMINE • GLYCERYL STEARATE SE • BEHENYL ALCOHOL • BEHENIC ACID • STEARIC ACID • BUTYLENE GLYCOL • BATYL ALCOHOL • THEANINE • PEG-30 PHYTOSTEROL • CARBOMER • DISODIUM EDTA • ALCOHOL • CELLULOSE GUM • SODIUM METAPHOSPHATE • BHT • TOCOPHEROL • METHYLPARABEN • ETHYLPARABEN • PHENOXYETHANOL • BENZOIC ACID • FRAGRANCE • TITANIUM DIOXIDE • MICA • 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 - 30 mL Bottle Carton

clé de peau
BEAUTÉ

PROTECTIVE FORTIFYING
EMULSION n

BROAD SPECTRUM
SPF 22
SUNSCREEN

30 mL 1 FL. OZ.



ÉMULSION FORTIFIANTE PROTECTRICE n

clé de peau
BEAUTÉ

PROTECTIVE FORTIFYING
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SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
G.L.O. 16332
www.cledepeau-beaute.com

縮小サイズ0.85倍 6mm/バー
12mm×33mm

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2次元
コード

16332-41-5041
AAA

Drug Facts (continued)

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QRコード

<http://cpb1982.com/16332CP>
See our website for more information.

Drug Facts (continued)

Inactive ingredients

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 CONCHOLIN PROTEIN - ISODONIS JAPONICUS LEAF/STALK EXTRACT - BUPLERURUM FALCATUM ROOT EXTRACT - PPG-17 - TRETHANOLAMINE - GLYCERYL STEARATE SE - BEHENYL ALCOHOL - BEHENIC ACID - STEARIC ACID - BUTYLENE GLYCOL - BATYL ALCOHOL - THEANINE - PEG-30 PHYTOSTEROL - CARBOMER - DISODIUM EDTA - ALCOHOL - CELLULOSE GUM - SODIUM METAPHOSPHATE - BHT - TOCOPHEROL - METHYLPARABEN - ETHYLPARABEN - PHENOXYETHANOL - BENZOIC ACID - FRAGRANCE - TITANIUM DIOXIDE - MICA - IRON OXIDES

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

CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N
avobenzene, octinoxate, octocrylene, and oxybenzone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-561
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	0.93 g in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.7528 g in 30 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	0.744 g in 30 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	0.372 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
XYLITOL (UNII: VCQ006KQ1E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
PEG-5 GLYCERYL STEARATE (UNII: 8CAC4NQ872)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TREHALOSE (UNII: B8WCK70T7I)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
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)	
PPG-17 (UNII: OV0Q322E0U)	
TROLAMINE (UNII: 9O3K93S3TK)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
DOCOSANOL (UNII: 9G1OE216XY)
BEHENIC ACID (UNII: H390488X0A)
STEARIC ACID (UNII: 4ELV7Z65AP)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
BATILOL (UNII: 39YR661C4U)
THEANINE (UNII: 8021PR16QO)
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
EDETATE DISODIUM (UNII: 7FLD91C86K)
ALCOHOL (UNII: 3K9958V90M)
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
METHYL PARABEN (UNII: A218C7H9T)
ETHYL PARABEN (UNII: 14255EXE39)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
BENZOIC ACID (UNII: 8SKN0B0MIM)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MICA (UNII: V8A1AW0880)
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:58411-561-10	1 in 1 CARTON	03/01/2020	
1		30 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)