

**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**

<b>Active ingredients</b>	<b>Purpose</b>
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 - 125 mL Container Carton**

clé de peau  
BEAUTÉ

PROTECTIVE FORTIFYING  
EMULSION

BROAD SPECTRUM  
SPF 22  
SUNSCREEN

125mL 4.2 FL. OZ.



CLÉ DE PEAU  
BEAUTÉ

PROTECTIVE FORTIFYING EMULSION n

**For skin with a radiance that evolves day by day.**

A daytime emulsion to boost skin intelligence\*, in order to activate the source of profound vitality and radiance. Replenishing all-day moisture helps to revive skin's natural resilience and glow for a fresh, radiantly youthful look.

\*Skin's innate ability to distinguish between good and bad stimuli, to achieve and maintain its ideal condition.

- Formulated with **Skin-Empowering Illuminator**, our exclusive ingredient to enhance skin intelligence.
- Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-COMEDOGENIC. DERMATOLOGIST-TESTED.

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SHISEIDO AMERICAS CORPORATION DIST.  
NEW YORK, NY 10017  
MADE IN U.S.A.  
GLO. 15398  
www.cledepeau-beaute.com

縮小サイズ0.85倍 10mm×16mm  
16mm×33mm

7 30852 15398 1



**Drug Facts (continued)**

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PROTECTIVE FORTIFYING EMULSION n



clé de peau  
BEAUTÉ

PROTECTIVE FORTIFYING  
EMULSION n  
BROAD SPECTRUM  
SPF 22  
SUNSCREEN

125mL 4.2 FL. OZ.

<http://cl872.com/15398AA>  
See our website  
for more information.

I5398-41-5040  
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:58411-454
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3200 mg in 125 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	9472 mg in 125 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2560 mg in 125 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1280 mg in 125 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
XYLITOL (UNII: VCQ006KQ1E)	
DIMETHICONE (UNII: 92RU3N3Y10)	
ISODODECANE (UNII: A8289P68Y2)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
PEG-5 GLYCERYL STEARATE (UNII: 8CAC4NQ872)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISO STEARIC 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)	

<b>SODIUM ACETYLATED HYALURONATE</b> (UNII: WN66R7GL93)
<b>ROSA ROXBURGHII FRUIT</b> (UNII: CVT1AA87FF)
<b>BUPLEURUM FALCATUM ROOT</b> (UNII: X04E310LUY)
<b>PPG-17</b> (UNII: OV0Q322E0U)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)
<b>BEHENIC ACID</b> (UNII: H390488X0A)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)
<b>BATILOL</b> (UNII: 39YR661C4U)
<b>THEANINE</b> (UNII: 8021PR16QO)
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>ALCOHOL</b> (UNII: 3K9958V90M)
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)
<b>SODIUM POLYMETAPHOSPHATE</b> (UNII: P1BM4ZH95L)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)
<b>ETHYLPARABEN</b> (UNII: 14255EXE39)
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>MICA</b> (UNII: V8A1AW0880)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-454-10	1 in 1 CARTON	02/01/2019	
1		125 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 final	part352	02/01/2019	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-454) , ANALYSIS(58411-454)

Revised: 10/2018

SHISEIDO AMERICAS CORPORATION