

**CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N- avobenzone, octinoxate, octocrylene, and oxybenzone cream  
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.*

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**clé de peau BEAUTÉ PROTECTIVE FORTIFYING CREAM n**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
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 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 ■

## **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 - 50 mL Container Carton**

clé de peau

BEAUTÉ

PROTECTIVE FORTIFYING CREAM n

BROAD SPECTRUM

SPF 22

SUNSCREEN

50mL NET WT. 1.8 OZ.

PROTECTIVE FORTIFYING CREAM



clé de peau  
BEAUTÉ

PROTECTIVE FORTIFYING CREAM n  
BROAD SPECTRUM  
SPF 22  
SUNSCREEN

50mL NET WT. 1.8 OZ.

**Drug Facts** (continued)

**Directions**

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## CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N

avobenzone, octinoxate, octocrylene, and oxybenzone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-857
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.031 g in 50 mL

<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.52595 g in 50 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.5775 g in 50 mL
<b>OXYBENZONE</b> (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1.031 g in 50 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>DIETHYLHEXYL SUCCINATE</b> (UNII: 69W9UMG3P8)	
<b>TREHALOSE</b> (UNII: B8WCK70T7I)	
<b>PEG/PPG-14/7 DIMETHYL ETHER</b> (UNII: 6DNW9T7YT2)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PEG/PPG-17/4 DIMETHYL ETHER</b> (UNII: 4ET18WJG5K)	
<b>PHYTOSTERYL MACADAMIATE</b> (UNII: 233VSF903M)	
<b>GINKGO</b> (UNII: 19FUJ2C58T)	
<b>ANGELICA ACUTILOBA ROOT</b> (UNII: 3W51R3EK30)	
<b>PAEONIA LACTIFLORA ROOT</b> (UNII: 3Z3866YW6P)	
<b>CRATAEGUS MONOGYNA FLOWER</b> (UNII: NT52AMP29J)	
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)	
<b>GLYCINE</b> (UNII: TE7660XO1C)	
<b>ONONIS SPINOSA ROOT</b> (UNII: FD2FMC53M1)	
<b>ROSA CANINA FRUIT</b> (UNII: 3TNW8D08V3)	
<b>ZANTHOXYLUM PIPERITUM FRUIT RIND</b> (UNII: 728JDI7G4M)	
<b>FAGUS SYLVATICA FLOWER BUD</b> (UNII: 6D5V13045W)	
<b>SODIUM ACETYLATED HYALURONATE</b> (UNII: VN66R7GL93)	
<b>PERILLA FRUTESCENS LEAF</b> (UNII: T4L5881Y68)	
<b>ROSA ROXBURGHII FRUIT</b> (UNII: CVT1AA87FF)	
<b>BUPLEURUM FALCATUM ROOT</b> (UNII: X04E310LUY)	
<b>BEHENETH-20</b> (UNII: BJ4GP2IFLN)	
<b>PPG-17</b> (UNII: OV0Q322E0U)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>THEANINE</b> (UNII: 8021PR16QO)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>SODIUM METAPHOSPHATE</b> (UNII: 532IUT7IRV)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	

<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-857-40	1 in 1 CARTON	07/01/2022	
1		50 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	07/01/2022	

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

Revised: 1/2023

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