

CLE DE PEAU BEAUTE UV PROTECTIVE N- avobenzone, homosalate, octisalate, and octocrylene 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.

clé de peau BEAUTÉ UV PROTECTIVE CREAM N

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.3%	Sunscreen
HOMOSALATE 10.0%	Sunscreen
OCTISALATE 5.0%	Sunscreen
OCTOCRYLENE 5.0%	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 ■ BUTYLENE GLYCOL ■ GLYCERIN ■ SILICA ■ GLYCERYL DIISOSTEARATE ■ ALCOHOL DENAT. ■ CAPRYLYL METHICONE ■ BEHENYL ALCOHOL ■ C30-45 ALKYL METHICONE ■ DIPROPYLENE GLYCOL ■ DIMETHICONE ■ AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER ■ XANTHAN GUM ■ TREHALOSE ■ TOCOPHERYL ACETATE ■ 2-O-ETHYL ASCORBIC ACID ■ SCUTELLARIA BAICALENSIS ROOT EXTRACT ■ GLYCINE ■ PEG/PPG-14/7 DIMETHYL ETHER ■ THYMUS SERPYLLUM EXTRACT ■ GARCINIA MANGOSTANA BARK EXTRACT ■ PANAX GINSENG ROOT EXTRACT ■ FAGUS SYLVATICA BUD EXTRACT ■ AMINOETHANESULFINIC ACID ■ BUPLEURUM FALCATUM ROOT EXTRACT ■ ANGELICA ACUTILOBA ROOT EXTRACT ■ HYDROLYZED CONCHIOLIN PROTEIN ■ HYDROLYZED SILK ■ PERILLA OCYMOIDES LEAF EXTRACT ■ POLYQUATERNIUM-51 ■ CRATAEGUS MONOGYNA FLOWER EXTRACT ■ SAXIFRAGA SARMENTOSA EXTRACT ■ GINKGO BILOBA LEAF EXTRACT ■ MENTHA PIPERITA (PEPPERMINT) LEAF EXTRACT ■ BEHENETH-20 ■ C30-45 OLEFIN ■ STEARYL ALCOHOL ■ DISODIUM EDTA ■ CARBOMER ■ POTASSIUM HYDROXIDE ■ TOCOPHEROL ■ SODIUM METAPHOSPHATE ■ BHT ■ ALCOHOL ■ SODIUM METABISULFITE ■ THEANINE ■ SYZYGIUM JAMBOS LEAF EXTRACT ■ PHENOXYETHANOL ■ FRAGRANCE ■ IRON OXIDES ■ TITANIUM DIOXIDE ■ MICA ■

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 Tube Carton

clé de peau
BEAUTÉ

UV PROTECTIVE CREAM n

50+

BROAD SPECTRUM

SPF 50+

SUNSCREEN

50mL NET WT. 1.8 OZ.



CLE DE PEAU BEAUTE UV PROTECTIVE N
 avobenzone, homosalate, octisalate, and octocrylene cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-855

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.2167 g in 50 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5.29 g in 50 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2.645 g in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2.645 g in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERYL DIISOSTEARATE (UNII: 68BAV42LRC)	
ALCOHOL (UNII: 3K9958V90M)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DOCOSANOL (UNII: 9G1OE216XY)	
C30-45 ALKYL METHICONE (UNII: NFX970DSI2)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
DIMETHICONE (UNII: 92RU3N3Y10)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE/BEHENETH-25 METHACRYLATE CROSSPOLYMER (52000 MPA.S) (UNII: LZ291VH90H)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TREHALOSE (UNII: B8WCK70T7I)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
GLYCINE (UNII: TE7660XO1C)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
THYMUS SERPYLLUM WHOLE (UNII: 86H4S6K51N)	
GARCINIA MANGOSTANA BARK (UNII: N6A4WY566I)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
FAGUS SYLVATICA FLOWER BUD (UNII: 6D5V13045W)	
HYPOTAURINE (UNII: 5L08GE4332)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
PERILLA FRUTESCENS LEAF (UNII: T4L5881Y68)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 4:1) (UNII: X8Q92E1CPM)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
GINKGO (UNII: 19FUJ2C58T)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
C30-45 OLEFIN (UNII: 6DWD51M008)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

EDETATE DISODIUM (UNII: 7FLD91C86K)
CARBOMER HOMOPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: F68VH75CJC)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
TOCOPHEROL (UNII: ROZB2556P8)
SODIUM METAPHOSPHATE (UNII: 532IUT71RV)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
THEANINE (UNII: 8021PR16QO)
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
MICA (UNII: V8A1AW0880)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-855-60	1 in 1 CARTON	08/01/2022	
1		50 mL in 1 TUBE; 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	08/01/2022	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 1/2023

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