

CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING N- avobenzene, 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.

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
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 n




clé de peau
BEAUTÉ

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Drug Facts (continued)

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<http://ci872.com/15400AA>
See our website for more information.



CLÉ DE PEAU BEAUTÉ
PROTECTIVE FORTIFYING CREAM n

For skin with a radiance that evolves day by day.
A daytime cream to boost skin intelligence*, in order to activate the source of profound vitality and radiance. Intensely rich 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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AVOBENZONE 2.0%
OCTINOXATE 4.9%
OCTOCRYLENE 5.0%
OXYBENZONE 2.0%

Purpose

Sunscreen
Sunscreen
Sunscreen
Sunscreen

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.
G.L.O. 15400
www.cledepeau-beaute.com

Drug Facts (continued)

Inactive ingredients

WATER-CYCLOPENTASILOXANE-GLYCERIN-DIMETHYLSILYLSEBACATE-BUTYLENE GLYCOL-DIETHYLHEXYL SUCCINATE-SD ALCOHOL 40-9-TREHALOSE-PEG/PPG-14/7 DIMETHYL ETHER-DIMETHICONE/NIYLY DIMETHICONE CROSSPOLYMER-TOCOPHERYL ACETATE-PEG/PPG-10/4 DIMETHYL ETHER-PHYTOSTERYL MACROHADATE-POLYQUINERMAN-91-QUINOD BULOBA LEAF EXTRACT-AMIGALCA ACUTYLOBA ROOT EXTRACT-PHEODRA ALERFLOIA ROOT EXTRACT-CRATAEGUS MONOGYMA FLOWER EXTRACT-PANAX GINSENG ROOT EXTRACT-GLUCONE-ONONIS SPINOSA ROOT EXTRACT-HYDROLYZED SILK-ROSA CANINA FRUIT EXTRACT-ZNITHORYLUM PIPEUTUM PEEL EXTRACT-HIBISCUS ESCULENTUS FRUIT EXTRACT-FRAGUS SYLVATICUS FRUIT EXTRACT-SCOBUM ACETYLATED HYALURONATE-PIBILLA OXYMIDES LEAF EXTRACT-ROSA ROZBURGIB FRUIT EXTRACT-HYDROLYZED CONCHODIN PROTEIN-ISODONS JAPONICUS LEAF/SOUL EXTRACT-DUPLEURUM FALCATUM ROOT EXTRACT-BEHENETH-20-PPG-41-SEHEMYL ALCOHOL-CARBOIMER-POLYSORBATE 80-TRIETHANOLAMINE-SCOBUM EDTA-SHEARYL ALCOHOL-HYDROXYPROPYL METHYLCELLULOSE STEAROXY ETHER-THIAMINE-SCOBUM CITRATE-ALCOHOL-SCOBUM METAPHOSPHATE-CITRIC ACID-BHT-TOCOPHEROL-PHENOLYETHANOL-METHYLPARABEN-BENZOIC ACID-FRAGRANCE-NIXA-TITANIUM DIOXIDE-IRON OXIDES

Other Information

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Questions or Comments?

Call toll free 1-800-906-7503



縮小サイズ0.85倍 10mmバー
16mm×33mm

7 30852 15400 1

15400-41-5040
AAA

Drug Facts (continued)

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avobenzone, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58 411-455
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1030 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2524 mg in 50 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2575 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1030 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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)	
ZANTHOXYLUM PIPERITUM FRUIT RIND (UNII: 728JDI7G4M)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
PPG-17 (UNII: OV0Q322E0U)	
DOCOSANOL (UNII: 9G1OE216XY)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
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: A218C7H9T)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
MICA (UNII: V8A1AW0880)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

FERRIC OXIDE RED (UNII: 1K09F3G675)

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

FERROSO FERRIC OXIDE (UNII: XM0M87F357)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-455-50	1 in 1 CARTON	02/01/2019	
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	02/01/2019	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-455) , ANALYSIS(58411-455)

Revised: 10/2018

SHISEIDO AMERICAS CORPORATION