

CLE DE PEAU BEAUTE SYNACTIF DAYTIME MOISTURIZER N- avobenzene, octinoxate, 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 SYNACTIF DAYTIME MOISTURIZER n

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 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

Other information

- protect this product in this container from excessive heat and direct sun.

Inactive Ingredients

WATER·XYLITOL·DIPROPYLENE GLYCOL·GLYCERIN·SD ALCOHOL 40-
B·DIPHENYLSILOXY PHENYL
TRIMETHICONE·ISODODECANE·SILICA·TRIETHYLHEXANOIN·HYDROGENATED
POLYDECENE·PPG-17·DIMETHICONE·METHYL AMINOMETHYLCYCLOHEXANE
CARBOXAMIDE HCl·XANTHAN GUM·TOCOPHERYL ACETATE·PEG/PPG-14/7 DIMETHYL
ETHER·PHYTOSTERYL MACADAMATE·GLYCYL GLYCINE·SODIUM ACETYLATED
HYALURONATE·SODIUM HYALURONATE·LAURYL BETAINE·NUPHAR JAPONICUM ROOT
EXTRACT·BUPLEURUM FALCATUM ROOT EXTRACT·GINKGO BILOBA LEAF
EXTRACT·CAMELLIA SINENSIS LEAF EXTRACT·BEHENETH-20·BEHENYL
ALCOHOL·HYDROGENATED PALM OIL·ELAEIS GUINEENSIS (PALM) KERNEL
OIL·STEARYL ALCOHOL·ELAEIS GUINEENSIS (PALM) OIL·BUTYLENE
GLYCOL·ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER·CARBOMER·PEG-10
DIMETHICONE·POTASSIUM HYDROXIDE·CELLULOSE GUM·SODIUM
METAPHOSPHATE·ALCOHOL·DISODIUM EDTA·BHT·ISOSTEARIC ACID·CINNAMOMUM
CASSIA BARK EXTRACT·TOCOPHEROL·CITRIC ACID·PHENOXYETHANOL·SODIUM
BENZOATE·FRAGRANCE·IRON OXIDES·

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 20 mL Bottle Carton

SYNACTIF

*Daytime
moisturizer*

BROAD SPECTRUM

SPF 19

SUNSCREEN

20mL .67 FL. OZ.

Daytime moisturizer



clé de peau
BEAUTÉ
SYNACTIF

DAYTIME
MOISTURIZER *n*
BROAD SPECTRUM
SPF 19
SUNSCREEN

READ INSERTION.

Drug Facts

Active ingredients

	Purpose
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 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

SHISEIDO AMERICAS
CORPORATION DIST.
NEW YORK, NY 10022
MADE IN U.S.A.
GLO. 11381

www.cledepeau-beaute.com



Drug Facts (continued)

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

Drug Facts (continued)

Inactive ingredients

WATER · XYLITOL · DIPROPYLENE GLYCOL · GLYCERIN · SD ALCOHOL 40-B · DIPHENYLSILOXY PHENYL TRIMETHICONE · ISODODECANE · SILICA · TRIETHYLHEXANOLIN · HYDROGENATED POLYDECENE · PPG-17 · DIMETHICONE · METHYL AMINOMETHYLCYCLOHEXANE CARBOXAMIDE HCl · XANTHAN GUM · TOCOPHERYL ACETATE · PEG/PPG-14/7 DIMETHYL ETHER · PHYTOSTERYL MACADAMATE · GLYCYL GLYCINE · SODIUM ACETYLATED HYALURONATE · SODIUM HYALURONATE · LAURYL BETAINE · NUPHAR JAPONICUM ROOT EXTRACT · BUPLEURUM FALCATUM ROOT EXTRACT · GINKGO BILOBA LEAF EXTRACT · CAMELLIA SINENSIS LEAF EXTRACT · BEHENETH-20 · BEHENYL ALCOHOL · HYDROGENATED PALM OIL · ELAÏS GUINEENSIS (PALM) KERNEL OIL · STEARYL ALCOHOL · ELAÏS GUINEENSIS (PALM) OIL · BUTYLENE GLYCOL · ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER · CARBOMER · PEG-10 DIMETHICONE · POTASSIUM HYDROXIDE · CELLULOSE GUM · SODIUM METAPHOSPHATE · ALCOHOL · DISODIUM EDTA · BHT · ISOSTEARIC ACID · CINNAMOMUM CASSIA BARK EXTRACT · TOCOPHEROL · CITRIC ACID · PHENOXYETHANOL · SODIUM BENZOATE · FRAGRANCE · 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

SYNACTIF

Daytime
moisturizer

BROAD SPECTRUM
SPF 19
SUNSCREEN

20mL .67 FL. OZ.

標準サイズ1.0倍 8mmバー
15mm×37.5mm

7 29238 11381 *

11381-41-5040
AAA

CLE DE PEAU BEAUTE SYNACTIF DAYTIME MOISTURIZER N

avobenzone, octinoxate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-237
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	518 mg in 20 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1532 mg in 20 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	414 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PALM OIL (UNII: 5QUO05548Z)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
ALCOHOL (UNII: 3K9958V90M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
CHINESE CINNAMON (UNII: WS4CQ062KM)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
ISODODECANE (UNII: A8289P68Y2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
PPG-17 (UNII: OV0Q322E0U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
METHYL AMINOMETHYLCYCLOHEXANE CARBOXYAMIDE HYDROCHLORIDE (UNII: ZV6O50F5CP)	

XANTHAN GUM (UNII: TTV12P4NEE)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
DIGLYCINE (UNII: 10525P22U0)
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
LAURYL BETAINE (UNII: Y4P927Q133)
NUPHAR JAPONICA ROOT (UNII: 3OPM78C6RQ)
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)
GINKGO (UNII: 19FUJ2C58T)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
BEHENETH-20 (UNII: BJ4GP2IFLN)
DOCOSANOL (UNII: 9G1OE216XY)
HYDROGENATED PALM OIL (UNII: 257THB963H)
PALM KERNEL OIL (UNII: B0S90M0233)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-237-10	1 in 1 CARTON	10/01/2014	
1		20 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 not final	part352	10/01/2014	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-237) , analysis(58411-237)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION