

CLE DE PEAU BEAUTE SHEER FLUID VEIL- avobenzone, 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 SHEER FLUID VEIL

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

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·SD ALCOHOL 40-B·BUTYLENE
GLYCOL·XYLITOL·DIMETHICONE·TALC·GLYCERIN·POLYMETHYL
METHACRYLATE·PEG/PPG-19/19 DIMETHICONE·HYDROGENATED
POLYISOBUTENE·XANTHAN GUM·ERYTHRITOL·SODIUM ACETYLATED

HYALURONATE·ROSA ROXBURGHII FRUIT EXTRACT·DIMETHICONE/VINYL
DIMETHICONE CROSSPOLYMER·HYDROLYZED CONCHIOLIN PROTEIN·HYDROLYZED
SILK·PPG-17·DISODIUM EDTA·PEG-60 GLYCERYL
ISOSTEARATE·TRIETHANOLAMINE·CARBOMER·ACRYLATES/C10-30 ALKYL ACRYLATE
CROSSPOLYMER·SODIUM METAPHOSPHATE·BHT·TOCOPHEROL·SODIUM
METABISULFITE·POLYMETHYLSILSESQUIOXANE·ALCOHOL·FRAGRANCE·IRON
OXIDES·MICA·TITANIUM DIOXIDE·

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 - 30 mL Tube Carton

clé de peau

BEAUTÉ

sheer fluid veil

BROAD SPECTRUM

SPF 21

SUNSCREEN

30mL 1 FL. OZ.

sheer fluid veil

Drug Facts
(continued)

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clé de peau
BEAUTÉ

sheer fluid veil

**BROAD SPECTRUM
SPF 21
SUNSCREEN**

swimming or sweating
reapply at least every 2 hours

30mL 1 FL. OZ.

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33303-41-5040
AAA

clé de peau
BEAUTÉ
SHEER FLUID VEIL
BROAD SPECTRUM SPF 21
SUNSCREEN
READ INSERTION.

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Uses

helps prevent sunburn

if used as directed with other sun protection

Drug Facts (continued)

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

GLO. 33303

www.cledepeau-beaute.com

This package is made using bagasse paper (a non-wood paper).



■ If you experience any medical help or contact a Poison Control Center right away.

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avobenzone, octinoxate, and octocrylene cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	771 mg in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2282 mg in 30 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	617 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
XYLITOL (UNII: VCQ006KQ1E)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TALC (UNII: 7SEV7J4R1U)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG/PPG-19/19 DIMETHICONE (UNII: EHH90CO7TL)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ERYTHRITOL (UNII: RA96B954X6)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
PPG-17 (UNII: OV0Q322E0U)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PEG-60 GLYCERYL ISO STEARATE (UNII: WQP0973914)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ALCOHOL (UNII: 3K9958V90M)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-206-10	1 in 1 CARTON	09/01/2014	
1		30 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	09/01/2014	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-206) , analysis(58411-206)