

CLE DE PEAU BEAUTE PROTECTIVE FORTIFYING- 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.

CLÉ DE PEAU BEAUTÉ PROTECTIVE FORTIFYING

CREAM

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
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 (AQUA/EAU)·CYCLOMETHICONE·GLYCERIN·DIISOPROPYL SEBACATE·BUTYLENE

GLYCOL·DIETHYLHEXYL SUCCINATE·SD ALCOHOL 40-B·PEG/PPG-14/7 DIMETHYL
ETHER·TREHALOSE·DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER·TOCOPHERYL
ACETATE·PEG/PPG-17/4 DIMETHYL ETHER·PHYTOSTERYL
MACADAMIATE·POLYQUATERNIUM-51·SODIUM ACETYLATED HYALURONATE·GINKGO
BILOBA LEAF EXTRACT·PAEONIA ALBIFLORA ROOT EXTRACT·CRATAEGUS
MONOGYNA FLOWER EXTRACT·CAFFEINE·SERINE·HYDROLYZED SILK·2-O-ETHYL
ASCORBIC ACID·BUPLEURUM FALCATUM ROOT EXTRACT·UNCARIA GAMBIR
EXTRACT·ROSA ROXBURGHII FRUIT EXTRACT·HYDROLYZED CONCHIOLIN
PROTEIN·BEHENETH-20·PPG-17·BEHENYL ALCOHOL·CARBOMER·POLYSORBATE
20·TRIETHANOLAMINE·DISODIUM EDTA·STEARYL ALCOHOL·HYDROXYPROPYL
METHYLCELLULOSE STEAROXY ETHER·THEANINE·SODIUM CITRATE·SODIUM
METAPHOSPHATE·CITRIC
ACID·BHT·ALCOHOL·TOCOPHEROL·PHENOXYETHANOL·METHYLPARABEN·BENZOIC
ACID·FRAGRANCE (PARFUM)·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 Jar Carton

clé de peau

BEAUTÉ

protective fortifying cream

BROAD SPECTRUM SPF 22 SUNSCREEN

DIN 02440806

50mL NET WT. 1.7 OZ.

crème fortifiante protectrice
protective fortifying cream




clé de peau
BEAUTÉ

crème fortifiante protectrice
F.P.S. 22 À LARGE SPECTRE ÉCRAN SOLAIRE
protective fortifying cream
BROAD SPECTRUM SPF 22 SUNSCREEN

DIN 02440806

50mL NET WT. 1.7 OZ.



70x70x68m/m

clé de peau BEAUTÉ
 CRÈME FORTIFIANTE PROTECTRICE
 F.P.S. 22 À LARGE SPECTRE ÉCRAN SOLAIRE
 PROTECTIVE FORTIFYING CREAM
 BROAD SPECTRUM SPF 22 SUNSCREEN

Informations du Médicament

Ingrédients Médicinaux

Ingrédients Médicinaux	But
AVOBENZONE 2.0%	Écransolaire
OCTINOXATE 4.9%	Écransolaire
OCTOCRYLENE 5.0%	Écransolaire
OXYBENZONE 2.0%	Écransolaire

Drug Facts

Active (Medicinal) Ingredients

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SHISEIDO AMERICAS CORPORATION DIST. NEW YORK, NY 10022
 MADE IN U.S.A.; FABRIQUE AUX E.U. DIST: SHISEIDO (CANADA) INC.
 MARKHAM, ONTARIO L3R 5P9 CANADA

GLO. 11831

www.cledepeau-beaute.com

Informations du Médicament (suite) / Drug Facts (continued)

Ingrédients Non-médicinaux / Inactive (Non-medicinal) Ingredients

WATER(AQUA/EAU) - CYCLOMETHICONE - GLYCERIN - DIMETHYL SEBACATE - BUTYLENE GLYCOL - DIMETHYLHEXYL SUCCINATE -
 SD ALCOHOL 40-8 - PEG/PPG-14/7 DIMETHYL ETHER - TREHALOSE - DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER - TOCOPHERYL ACETATE -
 PEG/PPG-17/4 DIMETHYL ETHER - PHYTOSTERYL MACADAMATE - POLYQUATERNIUM-51 - SODIUM ACETYLATED HYALURONATE -
 GINNGO BULBOA LEAF EXTRACT - PAEONIA ALBIFLORA ROOT EXTRACT - CRATAEGUS MONOGYNA FLOWER EXTRACT - CAFFEINE - SERINE - HYDROLYZED SILK -
 2-O-ETHYL ASCORBIC ACID - BUPLEURUM FALCATUM ROOT EXTRACT - UNCARIA GAMBIR EXTRACT - ROSA ROXBURGHII FRUIT EXTRACT -
 HYDROLYZED CONCHILUM PROTEIN - BEHENETH-20 - PPG-17 - BEHENYL ALCOHOL - CARBOMER - POLYSORBATE 20 - TRIETHANOLAMINE - DISODIUM EDTA -
 STEARYL ALCOHOL - HYDROXYPROPYL METHYLCELLULOSE STEAROXY ETHER - THEANINE - SODIUM CITRATE - SODIUM METAPHOSPHATE - CITRIC ACID - BHT -

ALCOHOL · TOCOPHEROL · PHENOXYETHANOL · METHYL PARABEN · BENZOIC ACID · FRAGRANCE (PARFUM) · MICA · TITANIUM DIOXIDE · IRON OXIDES

Informations du Médicament (suite)

Autre information ■ protéger ce produit dans ce contenant, de la chaleur intense et des rayons solaires directs.

Questions or Comments? contactus@shiseidoca.com.

Drug Facts (continued)

Other Information ■ protect this product in this container from excessive heat and direct sun.

Questions or Comments? Call toll free 1-800-906-7503 (for U.S.A.)

LOT.

EXP.

縮小サイズ0.85倍 6mmバー
12mm×33mm

7 29238 11831 7 ■

AAA / ACA



Cet étui est fabriqué en bagasse
(papier non dérivé du bois).
This package is made using bagasse
paper (a non-wood paper).

Informations du Médicament (suite)

Usages

- aide à prévenir les coups de soleil
- si le produit est utilisé selon les instructions et avec d'autres mesures de protection contre le soleil (voir le Mode d'emploi), le risque de cancer de la peau et de vieillissement prématuré de la peau causé par le soleil est réduit

Mises en garde

Pour usage externe seulement

Ne pas utiliser sur la peau endommagée ou présentant des lésions

Éviter tout contact avec les yeux. Rincer à l'eau le cas échéant

En présence d'une éruption cutanée, cesser l'utilisation et consulter un professionnel de la santé

Garder hors de portée des enfants. En cas d'ingestion, consulter un médecin immédiatement ou appeler un centre antipoison

Modes d'emploi

Usage écran solaire:

- appliquer abondamment 15 minutes avant l'exposition au soleil
- utiliser un écran solaire résistant à l'eau lors d'une activité aquatique ou s'il y a transpiration
- appliquer de nouveau au moins toutes les 2 heures
- **Mesure de protection contre le soleil.** Passer du temps au soleil augmente le risque de cancer de la peau et de vieillissement prématuré de la peau. Afin de diminuer ce risque, il convient d'utiliser régulièrement un écran solaire avec un FPS à large spectre d'au moins 15 et d'appliquer d'autres mesures de protection contre le soleil, telles que:
 - limiter le temps passé au soleil, notamment entre 10 et 14 heures
 - porter des chemises à manches longues, des pantalons, un chapeau et des lunettes de soleil
- pour les enfants âgés de moins de 6 mois, consulter un professionnel de la santé

Drug Facts (continued)

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avobenzone, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-258
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1020 mg in 50 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2499 mg in 50 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	2550 mg in 50 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	1020 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
TREHALOSE (UNII: B8WCK70T7I)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GINKGO (UNII: 19FUJ2C58T)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
CAFFEINE (UNII: 3G6A5W338E)	
SERINE (UNII: 452VLY9402)	
2-O-ETHYL ASCORBIC ACID (UNII: 801M14RK9K)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
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 (UNII: 1Q73Q2JULR)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
.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)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-258-50	1 in 1 CARTON	02/01/2016	
1		50 mL in 1 JAR; 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	02/01/2016	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-258) , analysis(58411-258)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION