

CLE DE PEAU BEAUTE PROTECTIVE DAY- avobenzone, octinoxate, octocrylene emulsion
Shiseido Americas Corporation

cle de peau BEAUTE Protective Day

☐ Drug Facts

☐ Drug Facts

Avobenzone 2.5%
Octinoxate 4.9%
Octocrylene 5.0%

☐ Purpose

Sunscreen
Sunscreen
Sunscreen

- 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.

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

WATER □ DIPROPYLENE GLYCOL □ BUTYLENE GLYCOL □ ALCOHOL DENAT. □ GLYCERIN □
 DIISOPROPYL SEBACATE □ C12-15 ALKYL BENZOATE □ SILICA □ DIGLYCERIN □
 DIMETHICONE □ TREHALOSE □ POTASSIUM METHOXSALICYLATE □ PHYTOSTERYL
 MACADAMIATE □ PEG-6 □ PEG-32 □ ORYZANOL □ TOCOPHERYL ACETATE □ PEG/PPG-17/4
 DIMETHYL ETHER □ TRIMETHYLSILOXYSILICATE □ GINKGO BILOBA LEAF EXTRACT □
 CRATAEGUS MONOGYNA FLOWER EXTRACT □ PANAX GINSENG ROOT EXTRACT □
 ONONIS SPINOSA ROOT EXTRACT □ HYDRANGAEA SERRATA LEAF EXTRACT □ ROSA
 CANINA FRUIT EXTRACT □ SAXIFRAGA SARMENTOSA EXTRACT □ ZANTHOXYLUM
 PIPERITUM PEEL EXTRACT □ HIBISCUS ESCULENTUS FRUIT EXTRACT □ SODIUM
 ACETYLATED HYALURONATE □ ROSA ROXBURGHII FRUIT EXTRACT □ LILIUM CANDIDUM
 FLOWER EXTRACT □ BUPLEURUM FALCATUM ROOT EXTRACT □ PETROLATUM □
 HYDROGENATED POLYDECENE □ PEG-10 PHYTOSTEROL □ SUCCINOGLYCAN □ MICA □ PEG-6
 DISTEARATE □ BEHENETH-10 □ CARBOMER □ ALCOHOL □ PEG/PPG-19/19 DIMETHICONE □
 STEARIC ACID □ DEXTRIN PALMITATE/ETHYLHEXANOATE □ HYDROXYPROPYL
 METHYLCELLULOSE STEAROXY ETHER □ CERAMIDE NP □ POTASSIUM HYDROXIDE □ C13-16
 ISOPARAFFIN □ BHT □ SODIUM METAPHOSPHATE □ DISODIUM EDTA □ C10-13
 ISOPARAFFIN □ SODIUM METABISULFITE □ TOCOPHEROL □ PHENOXYETHANOL □
 FRAGRANCE □ TITANIUM DIOXIDE □ IRON OXIDES □ RED 33 □ YELLOW 5 □

Other Information

- protect this product in this container from excessive heat and direct sunlight

Questions or Comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 125 mL Bottle Carton

clé de peau

BEAUTÉ

PROTECTIVE DAY

EMULSION

BROAD SPECTRUM

SPF 25

SUNSCREEN

125mL 4.2 FL. OZ.



CLÉ DE PEAU
BEAUTÉ
PROTECTIVE DAY EMULSION

For radiant skin that evolves day by day.
A daytime moisturizing emulsion that helps boost skin's visible youth-protecting power. Day by day, skin feels increased plumpness and resilience building on its own, resulting in a healthier look.

- Harnesses our revolutionary **Day Rhythm Fine-Tune Technology**, inspired by chronobiology.
- Infused with **Radiant Lily Extract**^{*}, our exclusive ingredient for unlocking the power of Skin Intelligence^{**}.
- **NON-COMEDOGENIC. DERMATOLOGIST-TESTED.**

^{*}Lilium Candidum Flower Extract, Glycerin
^{**}Skin's innate ability to distinguish between good and bad stimuli, to achieve and maintain its ideal condition.

Drug Facts

Active Ingredients	Purpose
Avobenzone 2.5%	Sunscreen
Octinoxate 4.9%	Sunscreen
Octocrylene 5.0%	Sunscreen

Uses

- helps prevent sunburn
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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

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

Drug Facts (continued)

Directions

- **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·Dipropylene Glycol·Butylene Glycol·Alcohol Denat.·Glycerin·Diisopropyl Sebacate·C12-15 Alkyl Benzoate·Silica·Diglycerin·Dimethicone·Trehalose·Potassium Methoxysalicylate·Phytosteryl Macadamiate·PEG-6·PEG-32·Oryzanol·Tocopheryl Acetate·PEG/PPG-17/4 Dimethyl Ether·Trimethylsiloxysilicate·Ginkgo Biloba Leaf Extract·Crataegus Monogyna Flower Extract·Panax Ginseng Root Extract·Ononis Spinosa Root Extract·Hydrangea Serrata Leaf Extract·Rosa Canina Fruit Extract·Saxifraga Sarmientosa Extract·Zanthoxylum Piperitum Peel Extract·Hibiscus Esculentus Fruit Extract·Sodium Acetylated Hyaluronate·Rosa Roxburghii Fruit Extract·Lilium Candidum Flower Extract·Bupleurum Falcatum Root Extract·Petrolatum·Hydrogenated Polydecene·PEG-10 Phytosterol·Succinoglycan·Mica·PEG-6 Distearate·Beheneth-10·Carbomer·Alcohol·PEG/PPG-19/19 Dimethicone·Stearic Acid·Dextrin Palmitate/Ethylhexanoate·Hydroxypropyl Methylcellulose Stearoxy Ether·Ceramide NP·Potassium Hydroxide·C13-16 Isoparaffin·BHT·Sodium Metaphosphate·Disodium EDTA·C10-13 Isoparaffin·Sodium Metabisulfite·Tocopherol·Phenoxyethanol·Fragrance·Titanium Dioxide·Iron Oxides·Red 33·Yellow 5

Other Information

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

Questions or Comments?
Call toll free 1-800-906-7503

<MI35037-811>

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16mm×33mm

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clé de peau
BEAUTÉ

PROTECTIVE DAY
EMULSION
BROAD SPECTRUM
SPF 25
SUNSCREEN

125mL 4.2 FL. OZ.



<http://cpb1982.com/22649CP>
See our website
for more information.

PRINCIPAL DISPLAY PANEL - 12 mL Bottle Carton

clé de peau
BEAUTÉ
PROTECTIVE DAY
EMULSION
BROAD SPECTRUM
SPF 25
SUNSCREEN



PRINCIPAL DISPLAY PANEL - 5 mL Bottle Carton

clé de peau

BEAUTÉ

PROTECTIVE DAY

EMULSION

BROAD SPECTRUM

SPF 25

SUNSCREEN



Drug Facts

Active Ingredients Purpose

Avobenzene 2.5%	Sunscreen
Octinoxate 4.9%	Sunscreen
Octocrylene 5.0%	Sunscreen

Use ■ 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

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Directions For sunscreen use: ■ apply liberally 15 minutes before sun exposure ■ use a water resistant sunscreen if swimming or sweating ►

SHISEIDO AMERICAS CORPORATION DIST.
NEW YORK, NY 10017
MADE IN U.S.A.

www.cledepeau-beaute.com

SAMPLE—NOT FOR SALE

Drug Facts (continued)

Directions ■ 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 • Dipropylene Glycol • Butylene Glycol • Alcohol Denat. • Glycerin • Diisopropyl Sebacate • C12-15 Alkyl Benzoate • Silica • Diglycerin • Dimethicone • Trehalose • Potassium Methoxysalicylate • Phytosterol • Macadamiate • PEG-6 • PEG-32 • Oryzanol • Tocopheryl Acetate • PEG/PPG-17/4 Dimethyl Ether • Trimethylsiloxysilicate • Ginkgo Biloba Leaf Extract • Crataegus Monogyna Flower Extract • Panax Ginseng Root Extract • Ononis Spinosa Root Extract • Hydrangea Serrata Leaf Extract • Rosa Canina Fruit Extract • Saxifraga Sarmientosa Extract • Zanthoxylum Piperitum Peel Extract ►



clé de peau
BEAUTÉ

PROTECTIVE DAY
EMULSION
BROAD SPECTRUM
SPF 25
SUNSCREEN

5mL .16 FL. OZ.

Drug Facts (continued)

Inactive ingredients

Hibiscus Esculentus Fruit Extract • Sodium Acetylated Hyaluronate • Rosa Roxburghii Fruit Extract • Lilium Candidum Flower Extract • Bupleurum Falcatum Root Extract • Petrolatum • Hydrogenated Polydecene • PEG-10 Phytosterol • Succinoglycan • Mica • PEG-6 Distearate • Beheneth-10 • Carbomer • Alcohol • PEG/PPG-19/19 Dimethicone • Stearic Acid • Dextrin • Palmitate/Ethylhexanoate • Hydroxypropyl Methylcellulose • Stearoyl Ether • Ceramide NP • Potassium Hydroxide • C12-16 Isoparaffin • BHT • Sodium Metaphosphate • Disodium EDTA • C10-13 Isoparaffin • Sodium Metabisulfite • Tocopherol • Phenoxyethanol • Fragrance • Titanium Dioxide • Iron Oxides • Red 33 • Yellow 5 •

Other Information

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

Questions or Comments?

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CLE DE PEAU BEAUTE PROTECTIVE DAY

avobenzene, octinoxate, octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-953
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.25 g in 125 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (ETHYLHEXYL METHOXYCINNAMATE - UNII:4Y5P7MUD51)	OCTINOXATE	6.38 g in 125 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6.51 g in 125 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
SILICA (UNII: ETJ7Z6XBU4)	
DIGLYCERIN (UNII: 3YC120743U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TREHALOSE (UNII: B8WCK70T7I)	
POTASSIUM METHOXY SALICYLATE (UNII: 5G3H7U4Y7F)	
PHYTOSTERYL MACADAMIATE (UNII: 233VSF903M)	
PEG-6 (UNII: 5655G9Y8AQ)	
PEG-32 (UNII: 1212Z7S33A)	
ORYZANOL (UNII: SST9XCL51M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG/PPG-17/4 DIMETHYL ETHER (UNII: 4ET18WJG5K)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
GINKGO BILOBA LEAF OIL (UNII: Y5967KO1JH)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
PANAX GINSENG ROOT (UNII: CUQ3A77YXI)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
HYDRANGEA SERRATA LEAF (UNII: 2SFZ1X3QA9)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
ZANTHOXYLUM PIPERITUM FRUIT RIND (UNII: 728JDI7G4M)	
HIBISCUS ESCULENTUS SEED EXTRACT (UNII: 525G687TQW)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
ROSA ROXBURGHII FRUIT (UNII: CVT1AA87FF)	
LILIUM CANDIDUM FLOWER (UNII: COV655U2CJ)	
BUPLEURUM FALCATUM ROOT (UNII: X04E310LUY)	
PETROLATUM (UNII: 4T6H12BN9U)	
HYDROGENATED POLYDECENE (1500 CST) (UNII: 4YI0729529)	
SUCCINOGLYCAN (AGROBACTERIUM TUMEFACIENS) (UNII: YP632MQS35)	
MICA (UNII: V8A1AW0880)	
PEG-6 DISTEARATE (UNII: 8CU46UJ38C)	
BEHENETH-10 (UNII: 313S43DM16)	
CARBOMER (UNII: 0A5MM307FC)	
ALCOHOL (UNII: 3K9958V90M)	
PEG/PPG-19/19 DIMETHICONE (UNII: EHH90CO7TL)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CERAMIDE NP (UNII: 4370DF050B)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
C13-16 ISOPARAFFIN (UNII: LED42LZG6O)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM METAPHOSPHATE (UNII: 532IUT7IRV)	

TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-953-10	1 in 1 BOX	12/11/2025	
1		125 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:58411-953-11	1 in 1 BOX	02/02/2025	
2		12 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:58411-953-12	1 in 1 BOX	02/02/2025	
3		5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/02/2025	

Labeler - Shiseido Americas Corporation (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
Shiseido America Inc.		782677132	manufacture(58411-953) , analysis(58411-953)