

**CLE DE PEAU BEAUTE PROTECTIVE LIP TREATMENT SPF 25- avobenzene, octinoxate, and octocrylene emulsion
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 LIP TREATMENT
SPF 25**

Drug Facts

Active ingredients	Purpose
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen

Uses

- helps prevent sunburn

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

TRIETHYLHEXANOIN ■ DIISOSTEARYL MALATE ■ HYDROGENATED POLYISOBUTENE ■
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE ■ POLYETHYLENE ■
TRIIISOSTEARIN ■ MICROCRYSTALLINE WAX ■ BUTYLENE GLYCOL ■ WATER ■
GLYCERIN ■ POLYGLYCERYL-2 DIISOSTEARATE ■ TOCOPHERYL ACETATE ■ ARGANIA
SPINOSA KERNEL OIL ■ SODIUM HYALURONATE ■ CRATAEGUS MONOGYNA FLOWER
EXTRACT ■ THYMUS SERPYLLUM EXTRACT ■ SODIUM ACETYLATED HYALURONATE ■
AMINOETHANESULFINIC ACID ■ TREHALOSE ■ GLYCINE ■ STEARYL GLYCIRRHETINATE
■ PEG/PPG-14/7 DIMETHYL ETHER ■ POTENTILLA ERECTA ROOT EXTRACT ■ MENTHA
PIPERITA (PEPPERMINT) LEAF EXTRACT ■ ANGELICA ACUTILOBA ROOT EXTRACT ■
HYDROLYZED CONCHIOLIN PROTEIN ■ HYDROLYZED SILK ■ SILICA DIMETHYL
SILYLATE ■ TOCOPHEROL ■ SIMETHICONE ■ BHT ■ TRIMETHYLOLPROPANE
TRIETHYLHEXANOATE ■ METHICONE ■ TETRADECENE ■ SILICA ■ THEANINE ■ TIN
OXIDE ■ FRAGRANCE ■ IRON OXIDES ■ TITANIUM DIOXIDE ■ MICA ■

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 - 4 g Bottle Box

clé de peau
BEAUTÉ

PROTECTIVE
LIP TREATMENT

25
BROAD SPECTRUM
SPF 25
SUNSCREEN

4g NET WT. .14 OZ.



CLÉ DE PEAU BEAUTÉ
PROTECTIVE LIP TREATMENT
BROAD SPECTRUM SPF 25
SUNSCREEN

Drug Facts

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OCTINOXATE 4.9% Sunscreen
OCTOCRYLENE 3.0% Sunscreen

Use ■ 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

■ 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.
G.L.O. 19159
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
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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 ►

QRコード

<http://cpb1982.com/19159CP>
See our website
for more information.

PROTECTIVE LIP TREATMENT



clé de peau
BEAUTÉ

PROTECTIVE
LIP TREATMENT

25
BROAD SPECTRUM
SPF 25
SUNSCREEN

4g NET WT. .14 OZ.



Drug Facts (continued)

Inactive Ingredients

TRIETHYLHEXANOIN • DIISOSTEARYL
MALATE • HYDROGENATED
POLYISOBUTENE • PHYTOSTERYL/
OCTYLDODECYL LAUROYL
GLUTAMATE • POLYETHYLENE •
TRISOSTEARIN • MICROCRYSTALLINE
WAX • BUTYLENE GLYCOL • WATER •
GLYCERIN • POLYGLYCERYL-2
DISOSTEARATE • TOCOPHERYL
ACETATE • ARGANIA SPINOSA
KERNEL OIL • SODIUM HYALURONATE •
CRATAEGUS MONOGYNA FLOWER
EXTRACT • THYMUS SERPYLLUM
EXTRACT • SODIUM ACETYLATED
HYALURONATE •
AMINOETHANESULFINIC ACID •
TREHALOSE • GLYCINE • STEARYL
GLYCIRRHETINATE • PEG/PPG-14/7
DIMETHYL ETHER • POTENTILLA
ERECTA ROOT EXTRACT • MENTHA
PIPERITA (PEPPERMINT) LEAF
EXTRACT • ANGELICA ACUTILOBA
ROOT EXTRACT • HYDROLYZED
CONCHOLIN PROTEIN • HYDROLYZED
SILK • SILICA DIMETHYL SILYLATE •
TOCOPHEROL • SIMETHICONE • BHT •
TRIMETHYLOLPROPANE
TRIETHYLHEXANOATE • METHICONE •
TETRADECENE • SILICA • THEANINE •
TIN OXIDE • FRAGRANCE • IRON
OXIDES • TITANIUM DIOXIDE • MICA •

Other Information

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container from excessive heat
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Questions or Comments?

Call toll free 1-800-906-7503
<M103150-811>

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11mmX26mm

19159-41-5040
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CLE DE PEAU BEAUTE PROTECTIVE LIP TREATMENT SPF 25

avobenzene, octinoxate, and octocrylene emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-856
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	100 mg in 4 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	196 mg in 4 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	120 mg in 4 g

Inactive Ingredients

Ingredient Name	Strength
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
TRIISOSTEARIN (UNII: 71503RH8KG)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ARGAN OIL (UNII: 4V59G5UW9X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CRATAEGUS MONOGYNA FLOWER (UNII: NT52AMP29J)	
THYMUS SERPYLLUM WHOLE (UNII: 86H4S6K51N)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
HYPOTAURINE (UNII: 5L08GE4332)	
TREHALOSE (UNII: B8WCK70T7I)	
GLYCINE (UNII: TE7660XO1C)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
POTENTILLA ERECTA ROOT (UNII: BI896CKT6B)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ANGELICA ACUTILOBA ROOT (UNII: 3W51R3EK30)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIMETHYLOLPROPANE TRIETHYLHEXANOATE (UNII: B952ZGW1IL)	
METHICONE (20 CST) (UNII: 6777U11MKT)	

1-TETRADECENE (UNII: FW23481S7S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
THEANINE (UNII: 8021PR16QO)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-856-20	1 in 1 BOX	08/01/2022	
1	NDC:58411-856-10	4 g in 1 BOTTLE, GLASS; 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	08/01/2022	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 1/2023

SHISEIDO AMERICAS CORPORATION