

**CLE DE PEAU BEAUTE UV PROTECTIVE LIP TREATMENT- avobenzene, octinoxate, octocrylene, and oxybenzone stick  
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 UV PROTECTIVE LIP TREATMENT**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 4.9%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
OXYBENZONE 2.0%	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**

DIISOSTEARYL MALATE•TRIETHYLHEXANOIN•HYDROGENATED POLYISOBUTENE•TRIISOSTEARIN•PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE•POLYETHYLENE•MICROCRYSTALLINE WAX•WATER•BUTYLENE GLYCOL•GLYCERIN•POLYGLYCERYL-2 DIISOSTEARATE•TOCOPHERYL ACETATE•PEG/PPG-36/41 DIMETHYL ETHER•ARGANIA SPINOSA KERNEL OIL•STEARYL

GLYCYRRHETINATE•MORTIERELLA OIL•GINKGO BILOBA LEAF EXTRACT•THYMUS  
SERPYLLUM EXTRACT•PANAX GINSENG ROOT EXTRACT•SODIUM ACETYLATED  
HYALURONATE•SODIUM HYALURONATE•SILICA DIMETHYL SILYLATE•LITHIUM  
MAGNESIUM SODIUM  
SILICATE•TOCOPHEROL•SIMETHICONE•BHT•ALCOHOL•TRIMETHYLOLPROPANE  
TRIETHYLHEXANOATE•METHICONE•TETRADECENE•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

**PRINCIPAL DISPLAY PANEL - 4 g Bottle Carton**

**clé de peau**

**BEAUTÉ**

**30**

*UV protective*

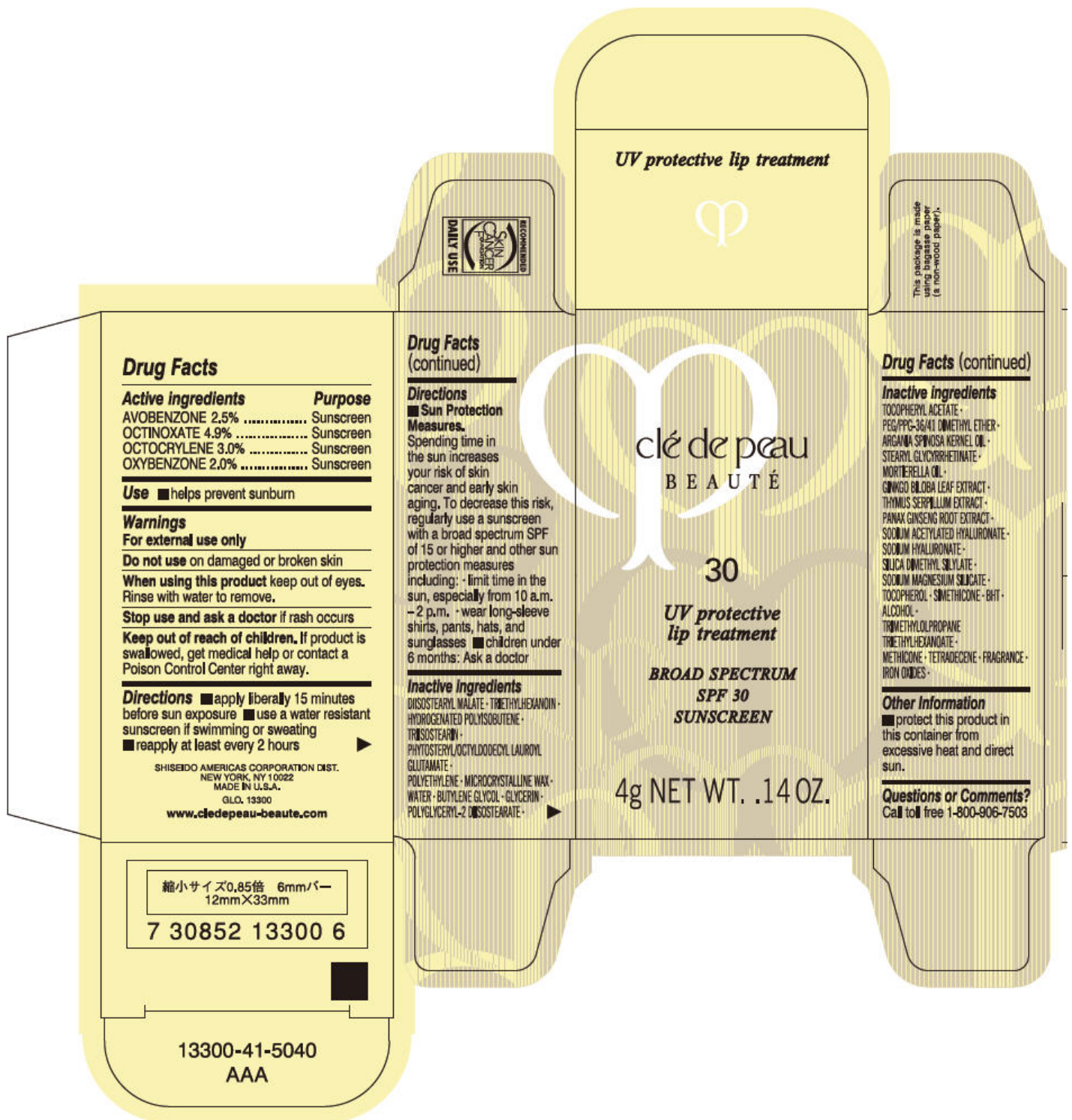
*lip treatment*

**BROAD SPECTRUM**

**SPF 30**

**SUNSCREEN**

4g NET WT. .14 OZ.



**Drug Facts**

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OXYBENZONE 2.0%	Sunscreen

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**Warnings**

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**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

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**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 10022  
MADE IN U.S.A.  
GLO, 13300  
[www.cledepeau-beaute.com](http://www.cledepeau-beaute.com)

縮小サイズ0.85倍 6mmバー  
12mmX33mm

7 30852 13300 6

13300-41-5040  
AAA

**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**

DISOSTEARYL MALATE - TRIETHYLHEXANOIN - HYDROGENATED POLYISOBUTENE - TRIISOSTEARYL - PHYTOSTEARYL/OCTYLDODECYL LAURYL GLUTAMATE - POLYETHYLENE - MICROCRYSTALLINE WAX - WATER - BUTYLENE GLYCOL - GLYCERIN - POLYGLYCERYL-2 DISOOSTEARATE

UV protective lip treatment



cle de peau  
BEAUTE

30

UV protective  
lip treatment

BROAD SPECTRUM  
SPF 30  
SUNSCREEN

4g NET WT. .14 OZ.

**Drug Facts (continued)**

**Inactive ingredients**

TOCOPHERYL ACETATE - PEG/PPG-36/41 DIMETHYL ETHER - ARGANIA SPINOSA KERNEL OIL - STEARYL GLYCERYLRHETINATE - MORTIERELLA OIL - GINKGO BILOBA LEAF EXTRACT - THYMUS SERPYLLUM EXTRACT - PANAX GINSENG ROOT EXTRACT - SODIUM ACETYLATED HYALURONATE - SODIUM HYALURONATE - SILICA DIMETHYL SILYLATE - SODIUM MAGNESIUM SILICATE - TOCOPHEROL - DIMETHICONE - BHT - ALCOHOL - TRIMETHYLOLPROPANE - TRIETHYLHEXANOIN - METHICONE - TETRADECENE - FRAGRANCE - IRON OXIDES

**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 UV PROTECTIVE LIP TREATMENT**

avobenzene, octinoxate, octocrylene, and oxybenzone stick

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-288
<b>Route of Administration</b>	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
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	80 mg in 4 g

### Inactive Ingredients

Ingredient Name	Strength
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
TRIISOSTEARIN (UNII: 71503RH8KG)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
WATER (UNII: 059QF0KO0R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-2 DIISOSTEARATE (UNII: DG195GP57P)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
ARGAN OIL (UNII: 4V59G5UW9X)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
GINKGO (UNII: 19FUJ2C58T)	
THYMUS SERPYLLUM (UNII: 86H4S6K51N)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SILICA DIMETHYL SILYLATE (UNII: EU2PSPOG0W)	
LAPONITE (UNII: D703131383)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
TRIMETHYLOLPROPANE TRIETHYLHEXANO ATE (UNII: B952ZGW1IL)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-288-10	1 in 1 CARTON	02/01/2017	
1		4 g in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph not final	part352	02/01/2017	
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**Labeler - SHISEIDO AMERICAS CORPORATION (193691821)**

**Establishment**

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-288) , analysis(58411-288)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION