

**SHISEIDO THE SKINCARE PROTECTIVE LIP CONDITIONER- octinoxate lipstick
SHISEIDO AMERICA INC.**

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.

SHISEIDO THE SKINCARE PROTECTIVE LIP CONDITIONER

Drug Facts

ACTIVE INGREDIENT

OCTINOXATE 4.9%

Purpose

Sunscreen

Use

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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
- children under 6 months: Ask a doctor

Inactive Ingredients

POLYGLYCERYL-2 TRIISOSTEARATE, TRIISOSTEARIN, MACADAMIA TERNIFOLIA SEED OIL, POLYETHYLENE, DIPHENYLSILOXY PHENYL TRIMETHICONE, TRIETHYLHEXANOIN, MICROCRYSTALLINE WAX, EUPHORBIA CERIFERA (CANDELILLA) WAX, WATER, SODIUM MAGNESIUM SILICATE, GLYCERIN, ARGININE HCl, XYLITOL, TOCOPHERYL ACETATE, ALLANTOIN, SODIUM HYALURONATE, PEG-10 DIMETHICONE, TOCOPHEROL, DIMETHICONE, DIISOSTEARYL MALATE, BHT, METHICONE, TETRADECENE, SILICA,

POLYSILICONE-2, FRAGRANCE, 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

SHISEIDO DIST.

NEW YORK • PARIS • MILANO

PRINCIPAL DISPLAY PANEL - 4g Cartridge Carton

SHISEIDO

The Skincare

Protective

Lip Conditioner

SPF 12

SUNSCREEN

4g NET WT. .14 OZ.

Protective
Lip Conditioner

Drug Facts
(continued)

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SHISEIDO

The Skincare

Protective
Lip Conditioner

SPF 12
SUNSCREEN

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■ children under 6 months:
Ask a doctor ▶

4g NET WT. .14 OZ.

7 30852 53032 4

53032-41-5044
AAE

Specially formulated by
Shiseido Laboratories,
Japan.

Drug Facts
(continued)

Inactive ingredients

POLYGLYCERYL-2 TRISOSTEARATE
TRISOSTEARATE

SHISEIDO
THE SKINCARE
PROTECTIVE LIP CONDITIONER
SPF 12

Drug Facts



MACADAMIA TERNIFOLIA SEED OIL •
POLYETHYLENE •
DIPHENYLSILOXY PHENYL TRIMETHICONE •
TRIETHYLHEXANOIN • MICROCRYSTALLINE WAX •
EUPHORBIA CERIFERA (CANDELLA) WAX •
WATER • SODIUM MAGNESIUM SILICATE •
GLYCERIN • ARGININE HCl • XYLITOL •
TOCOPHERYL ACETATE • ALLANTOIN •
SODIUM HYALURONATE • PEG-10 DIMETHICONE •
TOCOPHEROL • DIMETHICONE •
DISOCTEARYL MALATE • BHT • METHICONE •
TETRADECENE • SILICA • POLYSILOXANE-2 •
FRAGRANCE • MICA • TITANIUM DIOXIDE •
IRON OXIDES •

Other Information

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READ INSERTION.

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OCTINOXATE 4.9% Sunscreen

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SHISEIDO AMERICA INC.
NEW YORK, N.Y. 10022
MADE IN U.S.A.
SHISEIDO DIST.
NEW YORK • PARIS • MILANO
GLO. 53032
www.shiseido.com

34x24x73

1 2 3 4 5 6 7 8 9 0

SHISEIDO THE SKINCARE PROTECTIVE LIP CONDITIONER

octinoxate lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-134
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	196 mg in 4 g

Inactive Ingredients

Ingredient Name	Strength
TRISOSTEARIN (UNII: 71503RH8KG)	
MACADAMIA OIL (UNII: 515610SU8C)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
CANDELILLA WAX (UNII: WL0328HX19)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
XYLITOL (UNII: VCQ006KQ1E)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
ALLANTOIN (UNII: 344S277G0Z)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-134-20	1 in 1 CARTON		
1		4 g in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH NOT FINAL	part352	10/01/2012	
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Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-134) , ANALYSIS(52686-134)

Establishment

Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(52686-134)

Revised: 9/2012

SHISEIDO AMERICA INC.