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)

Warnings

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

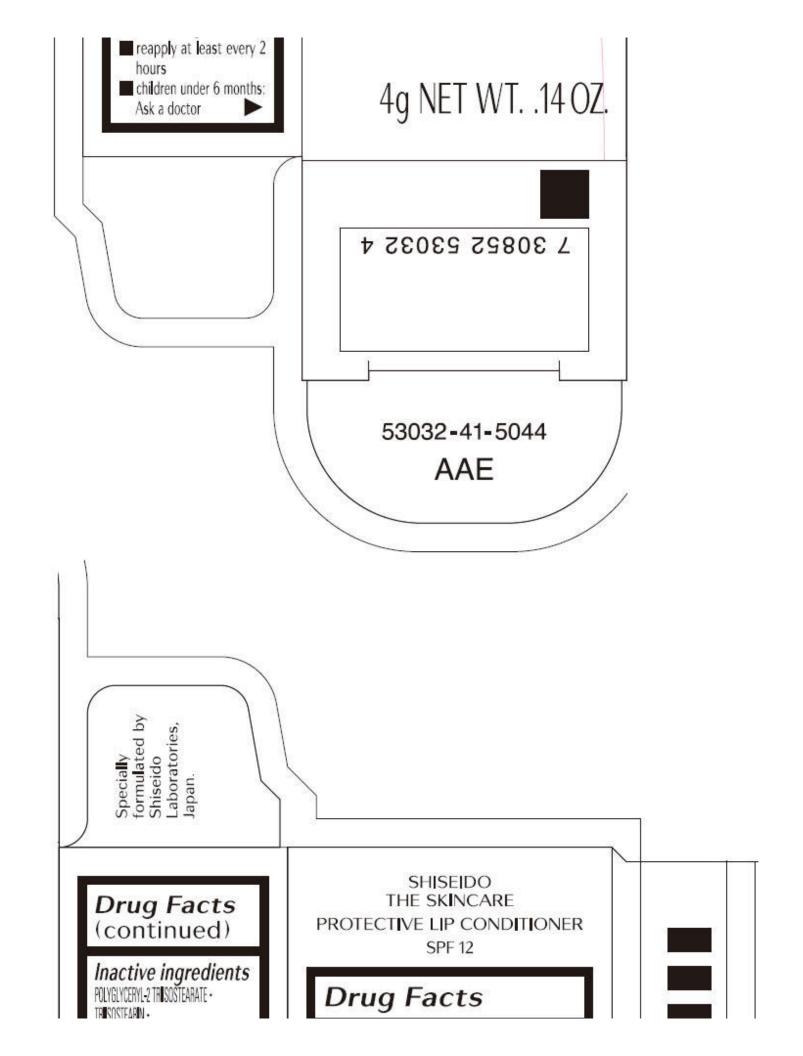
For sunscreen use:

- apply liberally 15 minutes before sun exposure
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MHINEIDO

The Skincare

Protective Lip Conditioner SPF 12 SUNSCREEN





Other Information

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

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

READ INSERTION.

Active ingredient Purpose OCTINOXATE 4.9% 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 help prevent sunburn, not skin cancer or early skin aging.

For external use only

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www.shiseido.com

34×24×73

SHISEIDO THE SKINCARE PROTECTIVE LIP CONDITIONER

octinoxate lipstick

Product Information

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

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (OCTINOXATE)	OCTINOXATE	196 mg in 4 g	

Inactive Ingredients	
Ingredient Name	Strength
TRIISOSTEARIN	
MACADAMIA O IL	
HIGH DENSITY PO LYETHYLENE	
DIPHENYLSILO XY PHENYL TRIMETHICO NE	
TRIETHYLHEXANO IN	
MICRO CRYSTALLINE WAX	
CANDELILLA WAX	
WATER	
GLYCERIN	
ARGININE HYDRO CHLO RIDE	
XYLITOL	
.ALPHATO COPHEROL ACETATE, DL-	
ALLANTOIN	
HYALURO NATE SO DIUM	
PEG-10 DIMETHICONE (600 CST)	
.ALPHATO COPHEROL	
DIMETHICONE	
DIISOSTEARYL MALATE	
BUTYLATED HYDRO XYTO LUENE	
METHICONE (20 CST)	
TETRADECENE	
SILICON DIO XIDE	
MICA	
TITANIUM DIO XIDE	
FERRIC O XIDE RED	
FERRIC OXIDE YELLOW	
FERROSOFERRIC OXIDE	

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 Informat	tion		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

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.