

**SHISEIDO SUN PROTECTION LIP TREATMENT- octinoxate and titanium dioxide 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 SUN PROTECTION LIP TREATMENT

Drug Facts

<i>ACTIVE INGREDIENTS:</i>	<i>Purpose</i>
OCTINOXATE 7.4%	Sunscreen
TITANIUM DIOXIDE 4.5%	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

TRIETHYLHEXANOIN, POLYGLYCERYL-2 TRIISOSTEARATE, TRIISOSTEARIN, HYDROGENATED POLYISOBUTENE, POLYETHYLENE, PEG/PPG-36/41 DIMETHYL ETHER, MICROCRYSTALLINE WAX, STEARYL GLYCYRRHETINATE, GLUTATHIONE, ZINC MYRISTATE, THIOTAUURINE, SODIUM ACETYLATED HYALURONATE, ALUMINUM HYDROXIDE, TOCOPHEROL, DIISOSTEARYL MALATE, SODIUM MAGNESIUM SILICATE, GLYCERIN, BHT, FRAGRANCE,

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 - 4g Cartridge Carton

SHI SEIDO

SPF 35

Sun Protection

Lip Treatment

SUNSCREEN

4g NET WT. .14 OZ.

Sun Protection
Lip Treatment
SPF 35

SHISEIDO

SPF 35
Sun Protection
Lip Treatment
SUNSCREEN

Drug Facts
(continued)

Inactive ingredients

TRIETHYLHEXANOIN •
POLYGLYCERYL-2
TRISOSTEARATE •
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THIOTAURINE •
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SODIUM MAGNESIUM SILICATE •
GLYCERIN • BHT • FRAGRANCE •

Other Information

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from excessive heat
and direct sun.

4g NET WT. .14 OZ.

Questions or Comments?

Call toll free
1-800-906-7503

7 30852 12559 9

12559-41-5041

AAB

SHISEIDO
SUN PROTECTION LIP TREATMENT
SPF 35

A highly nourishing lip balm that helps defend against powerful UVB rays while ensuring optimal moisture balance. Glides on smoothly to give lips softness and luminosity without any filmy residue or sensation of heaviness.

- Provides an exceptional retexturizing treatment for rough lips.
- May be worn alone or under lipstick.
- DERMATOLOGIST-TESTED.
- SPECIALLY FORMULATED BY SHISEIDO LABORATORIES, JAPAN.

Drug Facts

Active ingredients	Purpose
OCTINOXATE 7.4%	Sunscreen
TITANIUM DIOXIDE 4.5%	Sunscreen

Drug Facts
(continued)

Warnings

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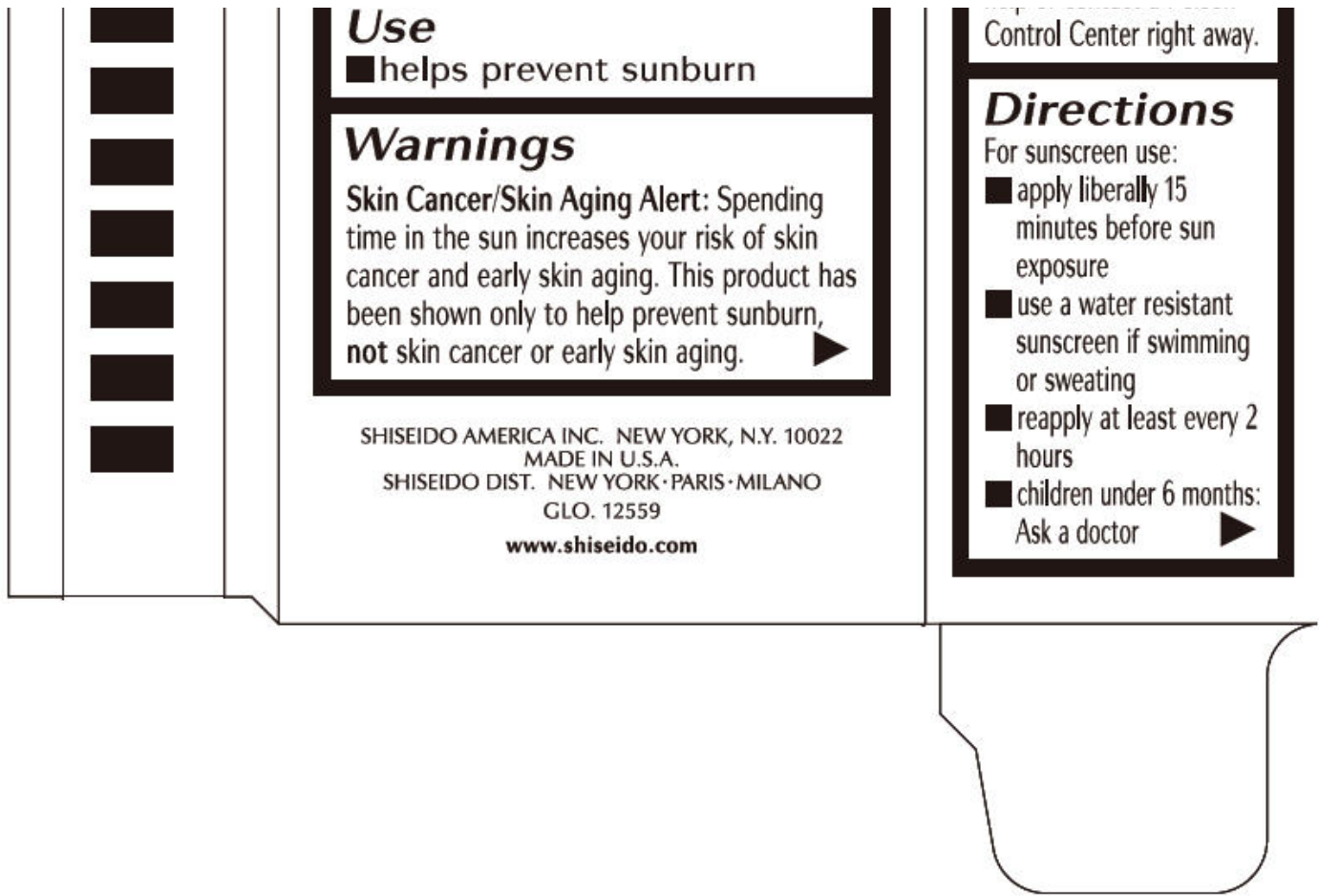
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1234567890

36x22x76



SHISEIDO SUN PROTECTION LIP TREATMENT

octinoxate and titanium dioxide lipstick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-642
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	296 mg in 4 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	180 mg in 4 g

Inactive Ingredients

Ingredient Name	Strength
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)	
TRIISO STEARIN (UNII: 71503RH8KG)	
HYDROGENATED POLYBUTENE (1300 MW) (UNII: 7D1YQ9Y5EZ)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	

STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
GLUTATHIONE (UNII: GAN16C9B8O)	
ZINC MYRISTATE (UNII: K09A9E2GGO)	
THIO TAURINE (UNII: NQZ2D7AO62)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
DIISO STEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-642-20	1 in 1 CARTON	10/01/2012	
1		4 g in 1 CARTRIDGE; 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	10/01/2012	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(52686-642) , analysis(52686-642)

Revised: 12/2018

SHISEIDO AMERICA INC.