

SHISEIDO SUN PROTECTION- octinoxate and titanium dioxide 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.

SHISEIDO SUN PROTECTION

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
OCTINOXATE 4.9%	Sunscreen
TITANIUM DIOXIDE 9.2%	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
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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

HYDROGENATED POLYDECENE, POLYMETHYL METHACRYLATE, DIMETHICONE, DIPHENYLSILOXY PHENYL TRIMETHICONE, TRIETHYLHEXANOIN, BARIUM SULFATE, KAOLIN, POLYETHYLENE, SORBITAN SESQUIISOSTEARATE, MICROCRYSTALLINE WAX, PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE, ZINC MYRISTATE, TOCOPHERYL ACETATE, THIOTAURINE, STEARYL GLYCYRRHETINATE, COPERNICIA CERIFERA (CARNAUBA) WAX, METHICONE, SILICA, ALUMINA, GLYCERIN,

TRIETHOXYCAPRYLYLSILANE, TOCOPHEROL, BHT, SODIUM CARBONATE, FRAGRANCE,
MICA, TITANIUM DIOXIDE,

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 - 9 g Cartridge Carton

SHISEIDO

Anti-Aging
Suncare

37

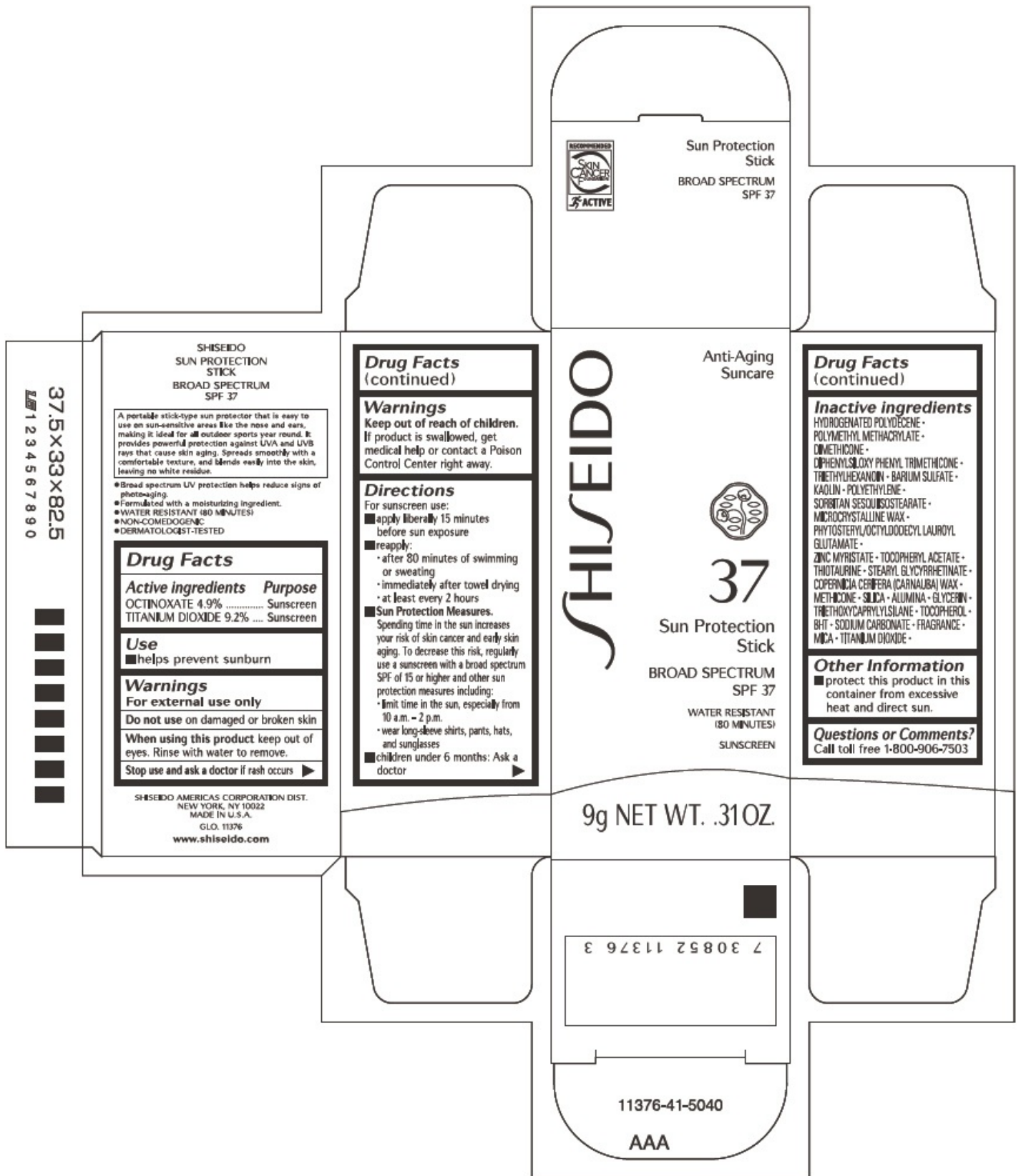
Sun Protection
Stick

BROAD SPECTRUM
SPF 37

WATER RESISTANT
(80 MINUTES)

SUNSCREEN

9g NET WT. .31 OZ.



SHISEIDO SUN PROTECTION

octinoxate and titanium dioxide stick

Product Information

Product Type

HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:58411-161

Route of Administration

TOPICAL

DEA Schedule

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (OCTINOXATE)	OCTINOXATE	441 mg in 9 g
TITANIUM DIOXIDE (TITANIUM DIOXIDE)	TITANIUM DIOXIDE	828 mg in 9 g

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED POLYDECENE (550 MW)	
DIMETHICONE	
DIPHENYLSILOXY PHENYL TRIMETHICONE	
TRIETHYLHEXANOIN	
BARIUM SULFATE	
KAOLIN	
HIGH DENSITY POLYETHYLENE	
MICROCRYSTALLINE WAX	
ZINC MYRISTATE	
.ALPHA.-TOCOPHEROL ACETATE	
THIO TAURINE	
STEARYL GLYCYRRHETINATE	
CARNAUBA WAX	
METHICONE (20 CST)	
SILICON DIOXIDE	
ALUMINUM OXIDE	
GLYCERIN	
TRIETHOXYCAPRYLYLSILANE	
TOCOPHEROL	
BUTYLATED HYDROXYTOLUENE	
SODIUM CARBONATE	
MICA	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-161-20	1 in 1 CARTON		
1		9 g in 1 CARTRIDGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	04/01/2014	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-161), ANALYSIS(58411-161)

Establishment

Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(58411-161)

Revised: 2/2014

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