

**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.*

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**SHISEIDO SUN PROTECTION**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
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**

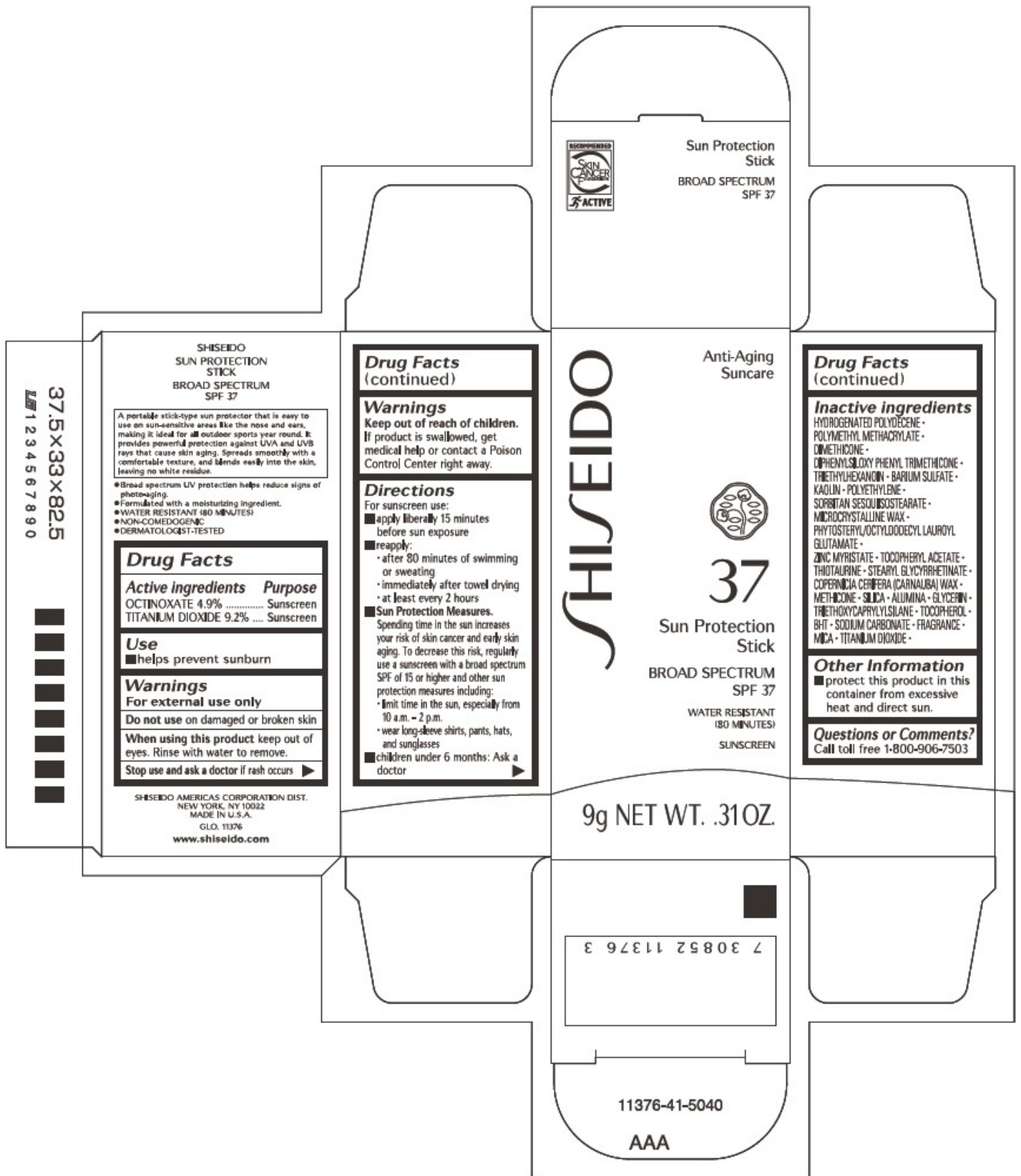
Sun Protection  
Stick

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

Item Code (Source)

NDC:58411-161

Route of Administration TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	441 mg in 9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	828 mg in 9 g

**Inactive Ingredients**

Ingredient Name	Strength
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPHENYLSILOXY PHENYL TRIMETHICONE (UNII: I445L28B12)	
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
KAOLIN (UNII: 24H4NWX5CO)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ZINC MYRISTATE (UNII: K09A9E2GGO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
THIO TAURINE (UNII: NQZ2D7AO62)	
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LM26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
SODIUM CARBONATE (UNII: 45P3261C7T)	
MICA (UNII: V8A1AW0880)	

**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)

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

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

Revised: 2/2014

SHISEIDO AMERICAS CORPORATION