

**SHISEIDO UV PROTECTIVE FOUNDATION FAIR IVORY- octinoxate and titanium dioxide stick**

**SHISEIDO UV PROTECTIVE FOUNDATION FAIR OCHRE- octinoxate and titanium dioxide stick**

**SHISEIDO UV PROTECTIVE FOUNDATION BEIGE- octinoxate and titanium dioxide stick**

**SHISEIDO UV PROTECTIVE FOUNDATION OCHRE- 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 UV PROTECTIVE FOUNDATION**

***Drug Facts***

<b><i>Active ingredients</i></b>	<b><i>Purpose</i></b>
OCTINOXATE 2.9%	Sunscreen
TITANIUM DIOXIDE 7.2%	Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

**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**

MINERAL OIL, POLYMETHYL METHACRYLATE, DIMETHICONE, KAOLIN, TRIETHYLHEXANOIN, POLYETHYLENE, SORBITAN SESQUIISOSTEARATE, MICROCRYSTALLINE WAX, PEG/PPG-14/7 DIMETHYL ETHER, SAXIFRAGA SARMENTOSA EXTRACT, SODIUM HYALURONATE, SOPHORA ANGUSTIFOLIA ROOT EXTRACT, COPERNICIA CERIFERA (CARNAUBA) WAX, METHICONE, SILICA, WATER, ALUMINA, ALCOHOL, SODIUM MAGNESIUM SILICATE, HYDRATED SILICA, TRIETHOXYCAPRYLYLSILANE, ALUMINUM HYDROXIDE, ALUMINUM DISTEARATE, BUTYLENE GLYCOL, GLYCERIN, TOCOPHEROL, HYDROGEN DIMETHICONE, DISTEARYLDIMONIUM CHLORIDE, BHT, SYZYGIIUM JAMBOS LEAF EXTRACT, TIN OXIDE, FRAGRANCE, TITANIUM DIOXIDE, IRON OXIDES, MICA,

## **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 - Fair Ivory**

### **SHI SEIDO**

Anti-Aging  
Foundation

**37**

UV Protective  
Stick Foundation

BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

9g NET WT. .31 OZ.

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

Fair Ivory

Anti-Aging  
Foundation



37

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)  
SUNSCREEN

SHISEIDO

### **Drug Facts** (continued)

#### **Inactive ingredients**

MINERAL OIL • POLYMETHYL METHACRYLATE •  
DIMETHICONE • KAOLIN • TRIETHYLHEXANOIN •  
POLYETHYLENE • SORBITAN SESQUISOOSTEARATE •  
MICROCRYSTALLINE WAX •  
PEG/PPG-14/7 DIMETHYL ETHER •  
SAXIFRAGA SARMENTOSA EXTRACT •  
SODIUM HYALURONATE •  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •  
COPERNICIA CERIFERA (CARNAUBA) WAX •  
METHICONE • SILICA • WATER • ALUMINA • ALCOHOL •  
SODIUM MAGNESIUM SILICATE • HYDRATED SILICA •  
TRITHIOCAPRYLYLSILANE • ALUMINUM HYDROXIDE •  
ALUMINUM OOSTEARATE • BUTYLENE GLYCOL •  
GLYCERIN • TOCOPHEROL • HYDROGEN DIMETHICONE •  
DISTEARYLDIMONIUM CHLORIDE • BHT •  
SYZYGIUM JAMBOS LEAF EXTRACT • TIN OXIDE •  
FRAGRANCE • TITANIUM DIOXIDE • IRON OXIDES • MICA

#### **Other Information**

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

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

9g NET WT. .31OZ.



7 30852 11206 3

11206-41-5040

AAA

SHISEIDO  
UV PROTECTIVE STICK FOUNDATION  
BROAD SPECTRUM SPF 37

A foundation that protects skin from damage caused by external aggressors such as UV rays and dryness. Resistant to water and sebum, it provides a long lasting, natural-looking finish, while safeguarding skin's beauty for the future.

- Protects skin from UVA/UVB rays and helps reduce the risk of visible photo-aging, with exclusive SuperVeilUV 360™ technology.
  - Formulated with Profense CEL™, a complex of ingredients that reduces enzyme activity,\* cell damage\* and DNA damage\* linked to the formation of wrinkles and dark spots.
  - Provides a creamy touch and a dewy finish.
  - NON-COMEDOGENIC AND DERMATOLOGIST-TESTED
- \* in vitro test

**Drug Facts**

Active ingredients	Purpose
OCTINOXATE 2.9% .....	Sunscreen

**Drug Facts**  
(continued)

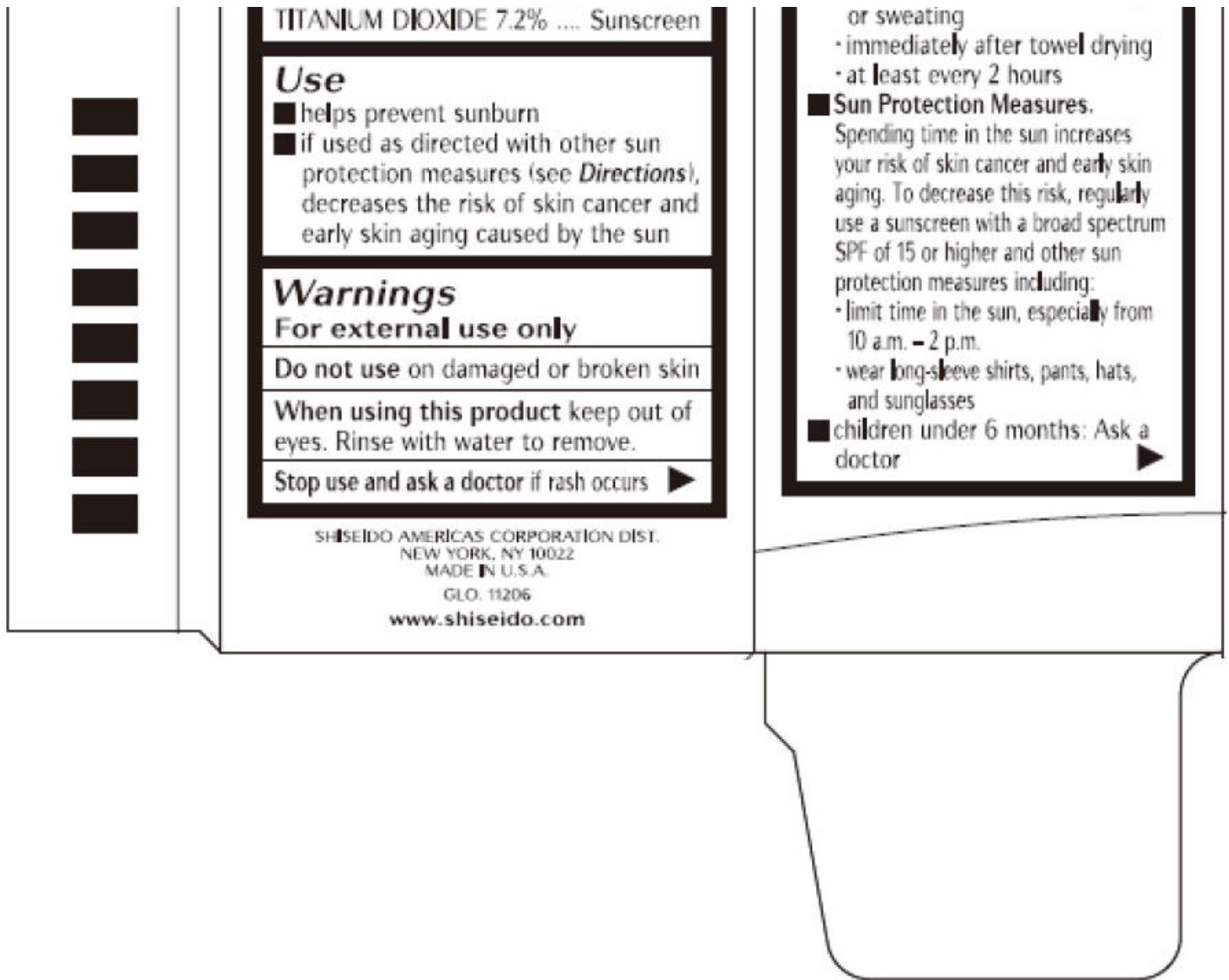
**Warnings**

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

37.5X33X82.5  
1 2 3 4 5 6 7 8 9 0



**PRINCIPAL DISPLAY PANEL - 9 g Cartridge Carton - Fair Ochre**

**SHI SEIDO**

Anti-Aging  
Foundation

**37**

UV Protective  
Stick Foundation

BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

9g NET WT. .31 OZ.

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

Fair Ochre

Anti-Aging  
Foundation

SHISEIDO



37

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

### Drug Facts (continued)

#### Inactive ingredients

MINERAL OIL • POLYMETHYL METHACRYLATE •  
DIMETHICONE • KAOLIN • TRIETHYLHEXANOIN •  
POLYETHYLENE • SORBITAN SESQUISOSEARATE •  
MICROCRYSTALLINE WAX •  
PEG/PPG-14/7 DIMETHYL ETHER •  
SAXIFRAGA SARMENTOSA EXTRACT •  
SODIUM HYALURONATE •  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •  
COPERNICIA CERIFERA (CARNAUBA) WAX •  
METHICONE • SILICA • WATER • ALUMINA • ALCOHOL •  
SODIUM MAGNESIUM SILICATE • HYDRATED SILICA •  
TRIMETHOXYCAPRYLYLSILANE • ALUMINUM HYDROXIDE •  
ALUMINUM OSTEARATE • BUTYLENE GLYCOL •  
GLYCERIN • TOCOPHEROL • HYDROGEN DIMETHICONE •  
DISTEARYLDIMONIUM CHLORIDE • BHT •  
SYZYGIUM JAMBOS LEAF EXTRACT • TIN OXIDE •  
FRAGRANCE • TITANIUM DIOXIDE • IRON OXIDES • MICA

#### Other Information

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

#### Questions or Comments?

Call toll free 1-800-906-7503

9g NET WT. .31OZ.

7 30852 11207 0

11207-41-5040

AAA

SHISEIDO  
UV PROTECTIVE STICK FOUNDATION  
BROAD SPECTRUM SPF 37

A foundation that protects skin from damage caused by external aggressors such as UV rays and dryness. Resistant to water and sebum, it provides a long lasting, natural-looking finish, while safeguarding skin's beauty for the future.

- Protects skin from UVA/UVB rays and helps reduce the risk of visible photo-aging, with exclusive SuperVeil-UV 360™ technology.
  - Formulated with Profense CEL™, a complex of ingredients that reduces enzyme activity,\* cell damage\* and DNA damage\* linked to the formation of wrinkles and dark spots.
  - Provides a creamy touch and a dewy finish.
  - NON-COMEDOGENIC AND DERMATOLOGIST-TESTED
- \* in vitro test

**Drug Facts**

Active ingredients	Purpose
OCTINOXATE 2.9% .....	Sunscreen
TITANIUM DIOXIDE 3.3% .....	Sunscreen

**Drug Facts**  
(continued)

**Warnings**

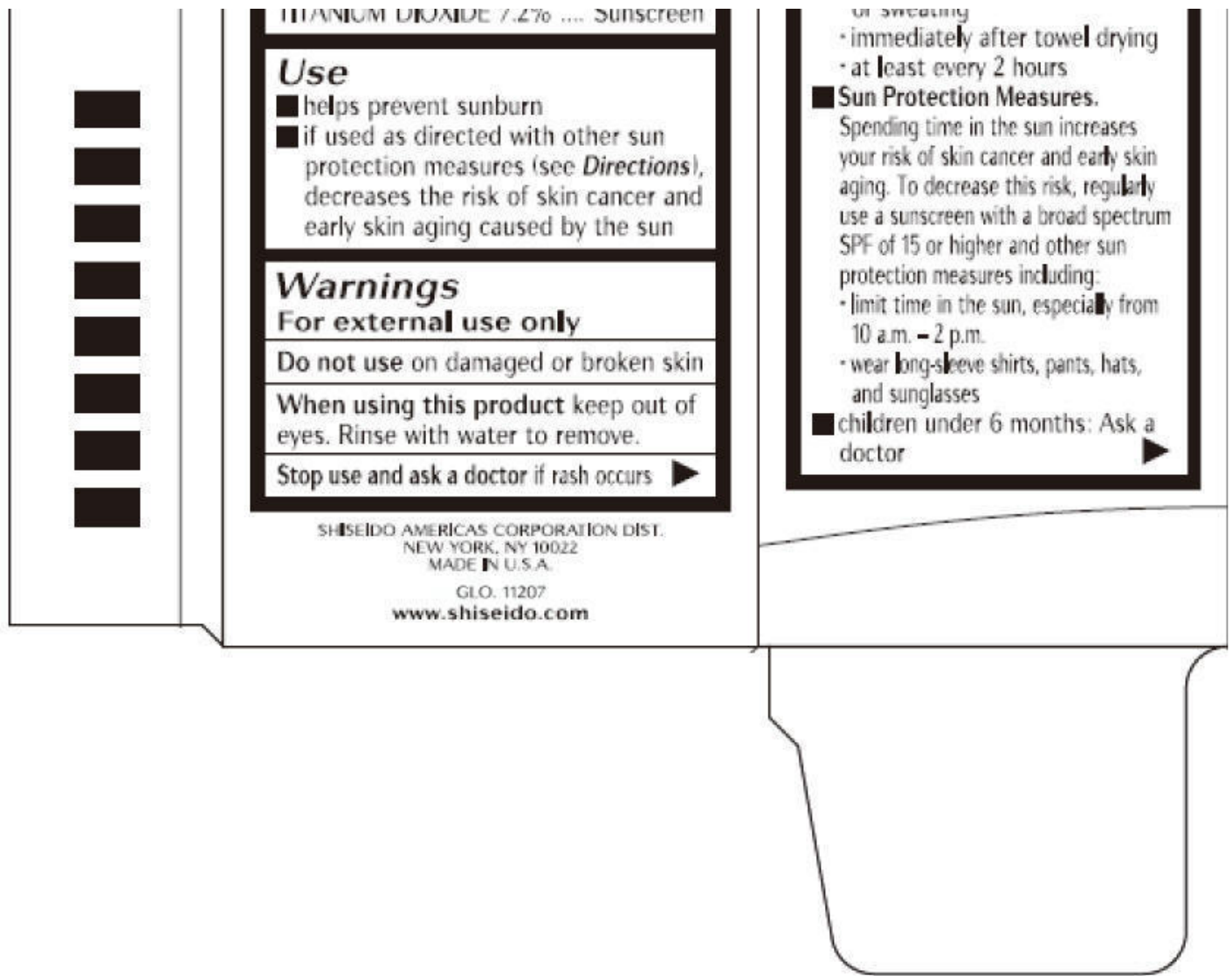
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

For sunscreen use:  
■ apply liberally 15 minutes before sun exposure  
■ reapply:  
- after 80 minutes of swimming or sweating

37.5X33X82.5

1 2 3 4 5 6 7 8 9 0



**PRINCIPAL DISPLAY PANEL - 9 g Cartridge Carton - Beige**

**SHI SEIDO**

Anti-Aging  
Foundation

**37**

UV Protective  
Stick Foundation

**BROAD SPECTRUM  
SPF 37**

**WATER RESISTANT  
(80 MINUTES)**

**SUNSCREEN**

**9g NET WT. .31 OZ.**



UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

Beige

SHISEIDO

Anti-Aging  
Foundation



37

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)  
SUNSCREEN

### Drug Facts (continued)

#### Inactive ingredients

MINERAL OIL • POLYMETHYL METHACRYLATE •  
DIMETHICONE • KAOLIN • TRIETHYLHEXANOLIN •  
POLYETHYLENE • SORBITAN SESQUISOOSTEARATE •  
MICROCRYSTALLINE WAX •  
PEG/PPG-14/7 DIMETHYL ETHER •  
SAXIFRAGA SARMENTOSA EXTRACT •  
SODIUM HYALURONATE •  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •  
COPERNICIA CERIFERA (CARNAUBA) WAX •  
METHICONE • SILICA • WATER • ALUMINA • ALCOHOL •  
SODIUM MAGNESIUM SILICATE • HYDRATED SILICA •  
TRIMETHOXYCAPRYLYLSILANE • ALUMINUM HYDROXIDE •  
ALUMINUM OOSTEARATE • BUTYLENE GLYCOL •  
GLYCERIN • TOCOPHEROL • HYDROGEN DIMETHICONE •  
DISTEARYLDIMONIUM CHLORIDE • BHT •  
SYZYGIUM JAMBOS LEAF EXTRACT • TIOXIDE •  
FRAGRANCE • TITANIUM DIOXIDE • IRON OXIDES • MICA •

#### Other Information

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

#### Questions or Comments?

Call toll free 1-800-906-7503

9g NET WT. .31 OZ.

7 30852 11208 7

11208-41-5040

AAA

SHISEIDO  
UV PROTECTIVE STICK FOUNDATION  
BROAD SPECTRUM SPF 37

A foundation that protects skin from damage caused by external aggressors such as UV rays and dryness. Resistant to water and sebum, it provides a long lasting, natural-looking finish, while safeguarding skin's beauty for the future.

- Protects skin from UVA/UVB rays and helps reduce the risk of visible photo-aging, with exclusive SuperVeil-UV 360™ technology.
- Formulated with Profense CEL™, a complex of ingredients that reduces enzyme activity,\* cell damage\* and DNA damage\* linked to the formation of wrinkles and dark spots.
- Provides a creamy touch and a dewy finish.
- NON-COMEDOGENIC AND DERMATOLOGIST-TESTED  
\* in vitro test

**Drug Facts**

Active ingredients	Purpose
OCTINOXATE 2.9%	Sunscreen

**Drug Facts**  
(continued)

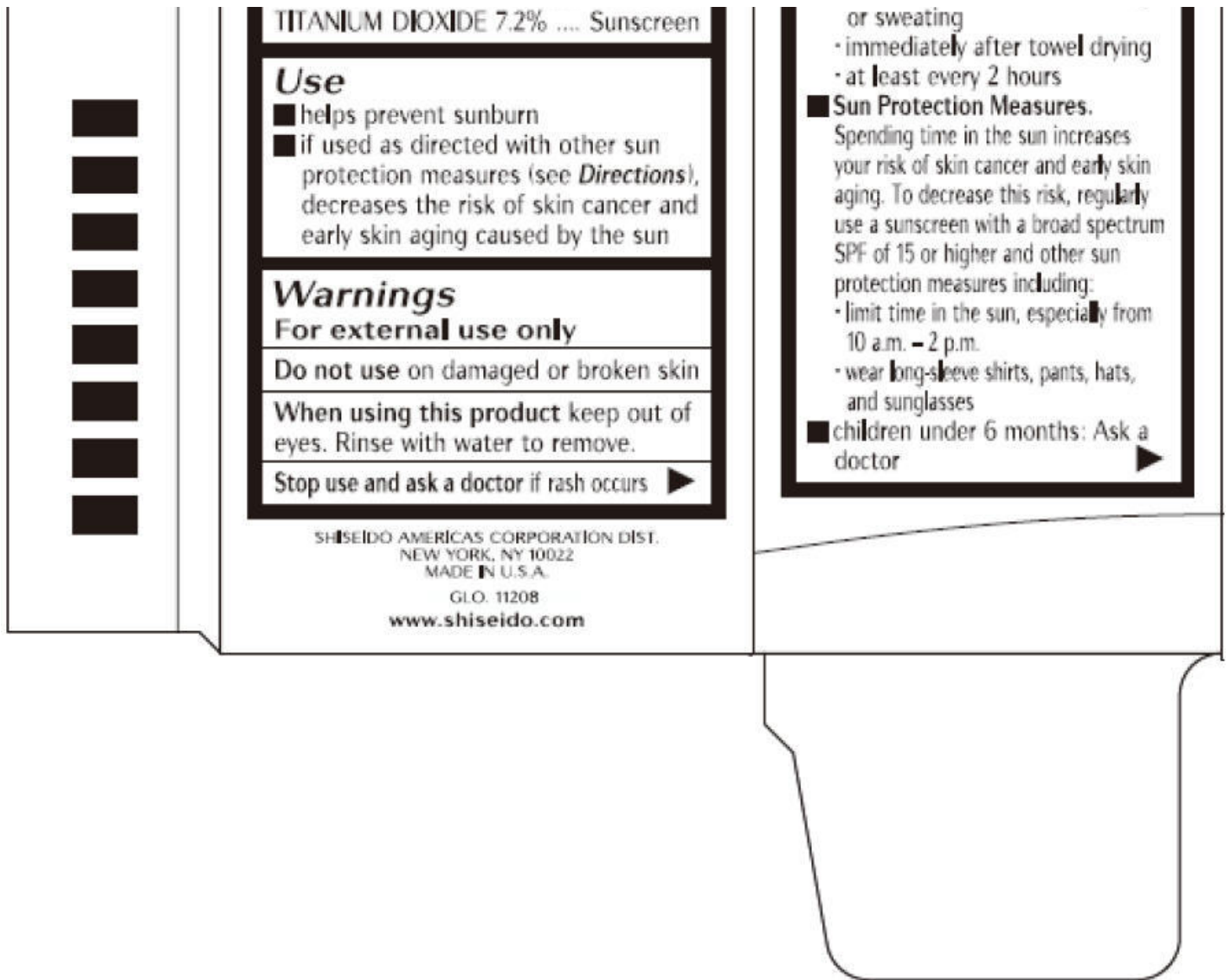
**Warnings**

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

37.5X33X82.5  
1 2 3 4 5 6 7 8 9 0



**PRINCIPAL DISPLAY PANEL - 9 g Cartridge Carton - Ochre**

**SHI SEIDO**

Anti-Aging  
Foundation

**37**

UV Protective  
Stick Foundation

BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)

SUNSCREEN

9g NET WT. .31 OZ.

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

Ochre

Anti-Aging  
Foundation



37

UV Protective  
Stick Foundation  
BROAD SPECTRUM  
SPF 37

WATER RESISTANT  
(80 MINUTES)  
SUNSCREEN

SHISEIDO

### Drug Facts (continued)

#### Inactive ingredients

MINERAL OIL • POLYMETHYL METHACRYLATE •  
DIMETHICONE • KAOLIN • TRIETHYLHEXANOLIN •  
POLYETHYLENE • SORBITAN SESQUISOOSTEARATE •  
MICROCRYSTALLINE WAX •  
PEG/PPG-14/7 DIMETHYL ETHER •  
SAXIFRAGA SARMENTOSA EXTRACT •  
SODIUM HYALURONATE •  
SOPHORA ANGUSTIFOLIA ROOT EXTRACT •  
COPERNICIA CERIFERA (CARNAUBA) WAX •  
METHICONE • SILICA • WATER • ALUMINA • ALCOHOL •  
SODIUM MAGNESIUM SILICATE • HYDRATED SILICA •  
TRITHIOCAPRYLYLSILANE • ALUMINUM HYDROXIDE •  
ALUMINUM OOSTEARATE • BUTYLENE GLYCOL •  
GLYCERIN • TOCOPHEROL • HYDROGEN DIMETHICONE •  
OOSTEARYLDIMONIUM CHLORIDE • BHT •  
SYZYGIUM JAMBOS LEAF EXTRACT • TIN OXIDE •  
FRAGRANCE • TITANIUM DIOXIDE • IRON OXIDES • MICA •

#### Other Information

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

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

9g NET WT. .31OZ.

7 30852 11209 4

11209-41-5040

AAA

SHISEIDO  
UV PROTECTIVE STICK FOUNDATION  
BROAD SPECTRUM SPF 37

A foundation that protects skin from damage caused by external aggressors such as UV rays and dryness. Resistant to water and sebum, it provides a long lasting, natural-looking finish, while safeguarding skin's beauty for the future.

- Protects skin from UVA/UVB rays and helps reduce the risk of visible photo-aging, with exclusive SuperVeil-UV 360™ technology.
- Formulated with Profense CEL™, a complex of ingredients that reduces enzyme activity,\* cell damage\* and DNA damage\* linked to the formation of wrinkles and dark spots.
- Provides a creamy touch and a dewy finish.
- NON-COMEDOGENIC AND DERMATOLOGIST-TESTED  
\* in vitro test

**Drug Facts**

Active ingredients	Purpose
OCTINOXATE 2.9%	Sunscreen

**Drug Facts**  
(continued)

**Warnings**

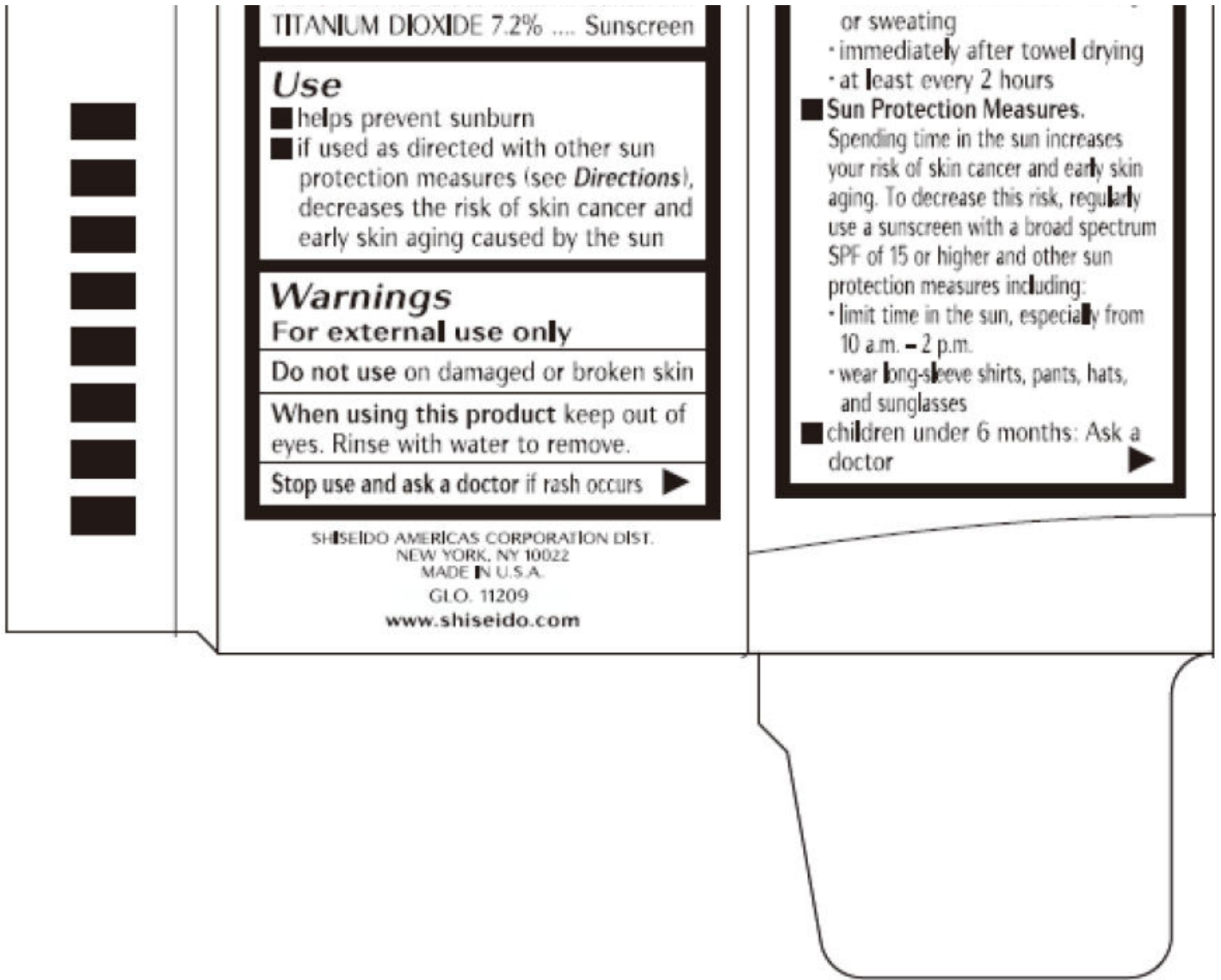
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming

37.5X33X82.5  
1 2 3 4 5 6 7 8 9 0



SHISEIDO UV PROTECTIVE FOUNDATION FAIR IVORY			
octinoxate and titanium dioxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-137
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)		OCTINOXATE	261 mg in 9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	648 mg in 9 g
Inactive Ingredients			
Ingredient Name			Strength
MINERAL OIL (UNII: T5L8T28FGP)			

DIMETHICONE (UNII: 92RU3N3Y1O)
KAOLIN (UNII: 24H4NWX5CO)
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)
CARNAUBA WAX (UNII: R12CBM0EIZ)
METHICONE (20 CST) (UNII: 6777U11MKT)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
WATER (UNII: 059QF0KO0R)
ALUMINUM OXIDE (UNII: LM26O6933)
ALCOHOL (UNII: 3K9958V90M)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERIN (UNII: PDC6A3C0OX)
TOCOPHEROL (UNII: R0ZB2556P8)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
STANNIC OXIDE (UNII: KM7N50LOS6)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-137-20	1 in 1 CARTON	02/01/2014	
1		9 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	02/01/2014	

## SHISEIDO UV PROTECTIVE FOUNDATION FAIR OCHRE

octinoxate and titanium dioxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-138

<b>Route of Administration</b>	TOPICAL
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<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	261 mg in 9 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	648 mg in 9 g

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>TRIETHYLHEXANO IN</b> (UNII: 7K3W1BIU6K)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>PEG/PPG-14/7 DIMETHYL ETHER</b> (UNII: 6DNW9T7YT2)	
<b>SAXIFRAGA STOLONIFERA LEAF</b> (UNII: O3TMV4903H)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>ALUMINUM DISTEARATE</b> (UNII: 7P1HP1B9UI)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573ZX3X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SYZYGIUM JAMBOS LEAF</b> (UNII: 407Z4W5LFF)	
<b>STANNIC OXIDE</b> (UNII: KM7N50LOS6)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>MICA</b> (UNII: V8A1AW0880)	

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58411-138-20	1 in 1 CARTON	02/01/2014	
1		9 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	02/01/2014	

## SHISEIDO UV PROTECTIVE FOUNDATION BEIGE

octinoxate and titanium dioxide stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-139
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	261 mg in 9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	648 mg in 9 g

### Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
KAOLIN (UNII: 24H4NWX5CO)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
WATER (UNII: 059QF0KO0R)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ALCOHOL (UNII: 3K9958V90M)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-139-20	1 in 1 CARTON	02/01/2014	
1		9 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	02/01/2014	

## SHISEIDO UV PROTECTIVE FOUNDATION OCHRE

octinoxate and titanium dioxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	261 mg in 9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	648 mg in 9 g

Inactive Ingredients	
Ingredient Name	Strength
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MICA (UNII: V8A1AW0880)	
MINERAL OIL (UNII: T5L8T28FGP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
KAOLIN (UNII: 24H4NWX5CO)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	

CARNAUBA WAX (UNII: R12CBM0EIZ)
METHICONE (20 CST) (UNII: 6777U11MKT)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
WATER (UNII: 059QF0KO0R)
ALUMINUM OXIDE (UNII: LM26O6933)
ALCOHOL (UNII: 3K9958V90M)
HYDRATED SILICA (UNII: Y6O7T4G8P9)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERIN (UNII: PDC6A3C0OX)
TOCOPHEROL (UNII: R0ZB2556P8)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
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SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
STANNIC OXIDE (UNII: KM7N50LOS6)
FERRIC OXIDE RED (UNII: 1K09F3G675)
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-140-20	1 in 1 CARTON	02/01/2014	
1		9 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	02/01/2014	

**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-137, 58411-138, 58411-139, 58411-140) , analysis(58411-137, 58411-138, 58411-139, 58411-140)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION