

SHISEIDO THE MAKEUP FOUNDATION I20- titanium dioxide stick  
SHISEIDO THE MAKEUP FOUNDATION I40- titanium dioxide stick  
SHISEIDO THE MAKEUP FOUNDATION I60- titanium dioxide stick  
SHISEIDO THE MAKEUP FOUNDATION B20- titanium dioxide stick  
SHISEIDO THE MAKEUP FOUNDATION B40- titanium dioxide stick  
SHISEIDO THE MAKEUP FOUNDATION B60- titanium dioxide stick  
SHISEIDO AMERICAS CORPORATION

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**SHISEIDO THE MAKEUP STICK FOUNDATION**

***Drug Facts***

**Active ingredients**

Titanium Dioxide 4.1%

**Purpose**

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- children under 6 months: ask a doctor
- **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**

CYCLOHEXASILOXANE • TRIETHYLHEXANOIN • DIMETHICONE • KAOLIN •  
CYCLOPENTASILOXANE • PARAFFIN • SORBITAN SESQUIISOSTEARATE • EUPHORBIA  
CERIFERA (CANDELILLA) WAX • PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE  
• TOCOPHERYL ACETATE • POLYMETHYL METHACRYLATE • COPERNICIA CERIFERA  
(CARNAUBA) WAX • ALUMINUM HYDROXIDE • STEARIC ACID • MICROCRYSTALLINE  
WAX • ALUMINA • GLYCERIN • TOCOPHEROL • ZINC OXIDE • BHT • FRAGRANCE •  
MICA • TITANIUM DIOXIDE • IRON OXIDES • ULTRAMARINES •

### **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 - 10 g Cartridge Carton - I 20**

I 20

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

120

NATURAL LIGHT IVORY  
GLO. 14942

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

**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  
■ use a water resistant sunscreen if swimming or sweating  
■ reapply 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.  
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■ children under 6 months: Ask a doctor ▶

SHISEIDO

120

The Makeup  
Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE -  
TRIETHYLHEXANOIN - DIMETHICONE -  
KAOLIN - CYCLOPENTASILOXANE -  
PARAFFIN -  
SORBITAN SESQUIISOSTEARATE -  
EUPHORBIA CERIFERA (CANDELLILLA)  
WAX -  
PHYTOSTERYL/OCTYLDODECYL  
LAUROYL GLUTAMATE -  
TOCOPHERYL ACETATE -  
POLYMETHYL METHACRYLATE -  
COPERNICIA CERIFERA (CARNAUBA)  
WAX -  
ALUMINUM HYDROXIDE - STEARIC ACID -  
MICROCRYSTALLINE WAX - ALUMINA -  
GLYCERIN - TOCOPHEROL - ZINC OXIDE -  
BHT - FRAGRANCE - MICA -  
TITANIUM DIOXIDE - IRON OXIDES -  
ULTRAMARINES -

**Other Information**

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**Questions or Comments?**

Call toll free 1-800-906-7503



SHISEIDO  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

**Flawless Skin And Beyond Through Advanced Luminous Technology.**

A creamy stick foundation that glides on effortlessly providing versatile coverage and a comfortable long-lasting lustrous finish while offering exceptional skincare benefits.

- Contains Multi-Nutrient Factor, an advanced moisturizer and energizer.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-CLOGGING TO PORES.
- DERMATOLOGIST-TESTED.

**Drug Facts**

**Active ingredient Purpose**  
TITANIUM DIOXIDE 4.1% ... Sunscreen

**Use**

■ helps prevent sunburn

**Warnings**

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Stop use and ask a doctor if rash occurs ▶

SHISEIDO AMERICAS  
CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.

www.shiseido.com



31X29X101  
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14942-40-5040

AAA



**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Carton - I 40**

I 40

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

140

NATURAL FAIR IVORY  
GLO. 14943

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

**Drug Facts**  
(continued)

**Warnings**

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**Directions**

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  - 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 ▶

SHISEIDO

140

The Makeup  
Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE •  
TRIETHYLHEXANOLIN • DIMETHICONE •  
KAOLIN • CYCLOPENTASILOXANE •  
PARAFFIN •  
SORBITAN SESQUISEOSTEARATE •  
EUPHORBIA CERIFERA (CANDELLILLA)  
WAX •  
PHYTOSTERYL/OCTYLDODECYL  
LAUROYL GLUTAMATE •  
TOCOPHERYL ACETATE •  
POLYMETHYL METHACRYLATE •  
COPERNICIA CERIFERA (CARNAUBA)  
WAX •  
ALUMINUM HYDROXIDE • STEARIC ACID •  
MICROCRYSTALLINE WAX • ALUMINA •  
GLYCERIN • TOCOPHEROL • ZINC OXIDE •  
BHT • FRAGRANCE • MICA •  
TITANIUM DIOXIDE • IRON OXIDES •  
ULTRAMARINES •

**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  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

**Flawless Skin And Beyond Through Advanced Luminous Technology.**

A creamy stick foundation that glides on effortlessly providing versatile coverage and a comfortable long-lasting lustrous finish while offering exceptional skincare benefits.

- Contains Multi-Nutrient Factor, an advanced moisturizer and energizer.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-CLOGGING TO PORES.
- DERMATOLOGIST-TESTED.

**Drug Facts**

**Active ingredient Purpose**  
TITANIUM DIOXIDE 4.1% ... Sunscreen

**Use**

■ helps prevent sunburn

**Warnings**

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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 ▶

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CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.

www.shiseido.com



31X29X101  
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14942-40-5040

AAA



**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Carton - I 60**

I 60

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

160

NATURAL DEEPIVORY  
GLO. 14944

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

**Drug Facts**  
(continued)

**Warnings**

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**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
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  - 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 ▶

SHISEIDO

160

The Makeup  
Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE -  
TRIETHYLHEXANOIN - DIMETHICONE -  
KAOLIN - CYCLOPENTASILOXANE -  
PARAFFIN -  
SORBITAN SESQUISEOSTEARATE -  
EUPHORBIA CERIFERA (CANDELLILLA)  
WAX -  
PHYTOSTERYL/OCTYLDODECYL  
LAUROYL GLUTAMATE -  
TOCOPHERYL ACETATE -  
POLYMETHYL METHACRYLATE -  
COPERNICIA CERIFERA (CARNAUBA)  
WAX -  
ALUMINUM HYDROXIDE - STEARIC ACID -  
MICROCRYSTALLINE WAX - ALUMINA -  
GLYCERIN - TOCOPHEROL - ZINC OXIDE -  
BHT - FRAGRANCE - MICA -  
TITANIUM DIOXIDE - IRON OXIDES -  
ULTRAMARINES -

**Other Information**

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**Questions or Comments?**

Call toll free 1-800-906-7503



SHISEIDO  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

**Flawless Skin And Beyond Through Advanced Luminous Technology.**

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- Contains Multi-Nutrient Factor, an advanced moisturizer and energizer.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-CLOGGING TO PORES.
- DERMATOLOGIST-TESTED.

**Drug Facts**

**Active ingredient Purpose**  
TITANIUM DIOXIDE 4.1% ... Sunscreen

**Use**

■ helps prevent sunburn

**Warnings**

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Stop use and ask a doctor if rash occurs ▶

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MADE IN U.S.A.  
[www.shiseido.com](http://www.shiseido.com)



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14942-40-5040

AAA



**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Carton - B 20**

B 20

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

B 20

NATURAL LIGHT BEIGE  
GLO. 14945

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

B 20

SHISEIDO

The Makeup

Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**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  
■ use a water resistant sunscreen if swimming or sweating  
■ reapply at least every 2 hours  
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• 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 ▶

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE - TRIETHYLHEXANOLIN - DIMETHICONE - KAOLIN - CYCLOPENTASILOXANE - PARAFFIN - SORBITAN SESQUISEOSTEARATE - EUPHORBIA CERIFERA (CANDELLA) WAX - PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE - TOCOPHERYL ACETATE - POLYMETHYL METHACRYLATE - COPERNICIA CERIFERA (CARNAUBA) WAX - ALUMINUM HYDROXIDE - STEARIC ACID - MICROCRYSTALLINE WAX - ALUMINA - GLYCERIN - TOCOPHEROL - ZINC OXIDE - BHT - FRAGRANCE - MICA - TITANIUM DIOXIDE - IRON OXIDES - ULTRAMARINES -

**Other Information**

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

**Questions or Comments?**

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SHISEIDO  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

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A creamy stick foundation that glides on effortlessly providing versatile coverage and a comfortable long-lasting lustrous finish while offering exceptional skincare benefits.

- Contains Multi-Nutrient Factor, an advanced moisturizer and energizer.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-CLOGGING TO PORES.
- DERMATOLOGIST-TESTED.

**Drug Facts**

**Active ingredient Purpose**  
TITANIUM DIOXIDE 4.1% ... Sunscreen

**Use**

■ 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 ▶

SHISEIDO AMERICAS CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.

www.shiseido.com



31X29X101  
1 2 3 4 5 6 7 8 9 0

14942-40-5040

AAA



**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Carton - B 40**

B 40

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

B 40

NATURAL FAIR BEIGE  
GLO. 14946

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

B 40

SHISEIDO

The Makeup  
Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**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  
■ use a water resistant sunscreen if swimming or sweating  
■ reapply 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 ▶

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE • TRIETHYLHEXANOIN • DIMETHICONE • KAOLIN • CYCLOPENTASILOXANE • PARAFFIN • SORBITAN SESQUISOESTEARATE • EUPHORBIA CERIFERA (CANDELLILLA) WAX • PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE • TOCOPHERYL ACETATE • POLYMETHYL METHACRYLATE • COPERNICIA CERIFERA (CARNAUBA) WAX • ALUMINUM HYDROXIDE • STEARIC ACID • MICROCRYSTALLINE WAX • ALUMINA • GLYCERIN • TOCOPHEROL • ZINC OXIDE • BHT • FRAGRANCE • MICA • TITANIUM DIOXIDE • IRON OXIDES • ULTRAMARINES •

**Other Information**

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**Questions or Comments?**

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SHISEIDO  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

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- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.
- NON-CLOGGING TO PORES.
- DERMATOLOGIST-TESTED.

**Drug Facts**

**Active ingredient Purpose**  
TITANIUM DIOXIDE 4.1% ... Sunscreen

**Use**

■ 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 ▶

SHISEIDO AMERICAS CORPORATION DIST.  
NEW YORK, NY 10022  
MADE IN U.S.A.

www.shiseido.com



31 X 29 X 101  
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14942-40-5040

AAA



**PRINCIPAL DISPLAY PANEL - 10 g Cartridge Carton - B 60**

B 60

SHISEIDO

The Makeup

Stick Foundation

BROAD SPECTRUM

SPF 20

sunscreen

10g NET WT. .35 OZ.

Stick Foundation

B 60

NATURAL DEEP BEIGE  
GLO. 14947

SPECIALLY  
FORMULATED BY  
SHISEIDO  
LABORATORIES,  
JAPAN.  
Printed on  
recycled paper.

B 60

**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  
■ use a water resistant sunscreen if swimming or sweating  
■ reapply at least every 2 hours  
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SHISEIDO

The Makeup  
Stick Foundation  
BROAD SPECTRUM  
SPF 20  
sunscreen

10g NET WT. .35 OZ.

**Drug Facts**  
(continued)

**Inactive ingredients**

CYCLOHEXASILOXANE •  
TRIETHYLHEXANOLIN • DIMETHICONE •  
KAOLIN • CYCLOPENTASILOXANE •  
PARAFFIN •  
SORBITAN SESQUISTEARATE •  
EUPHORBIA CERIFERA (CANDELLILLA)  
WAX •  
PHYTOSTERYL/OCTYLDODECYL  
LAURYL GLUTAMATE •  
TOCOPHERYL ACETATE •  
POLYMETHYL METHACRYLATE •  
COPERNICIA CERIFERA (CARNAUBA)  
WAX •  
ALUMINUM HYDROXIDE • STEARIC ACID •  
MICROCRYSTALLINE WAX • ALUMINA •  
GLYCERIN • TOCOPHEROL • ZINC OXIDE •  
BHT • FRAGRANCE • MICA •  
TITANIUM DIOXIDE • IRON OXIDES •  
ULTRAMARINES •

**Other Information**

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**Questions or Comments?**

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SHISEIDO  
THE MAKEUP  
STICK FOUNDATION  
BROAD SPECTRUM  
SPF 20

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- DERMATOLOGIST-TESTED.

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**Use**

■ helps prevent sunburn

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31X29X101  
1 2 3 4 5 6 7 8 9 0

14942-40-5040

AAA



# SHISEIDO THE MAKEUP FOUNDATION 120

titanium dioxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-458
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX43802MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 58411-458			

1	NDC:58411-458-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	

## SHISEIDO THE MAKEUP FOUNDATION I40

titanium dioxide stick

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-459
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

### Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
KAOLIN (UNII: 24H4NWX5CO)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
PARAFFIN (UNII: I9O0E3H2ZE)	
SORBITAN SESQUIISOSTEARATE (UNII: VU97D01BF9)	
CANDELILLA WAX (UNII: WL0328HX19)	
PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE (UNII: 65954KGO9Q)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MICA (UNII: V8A1AW0880)	

**FERRIC OXIDE RED** (UNII: 1K09F3G675)  
**FERRIC OXIDE YELLOW** (UNII: EX438O2MRT)  
**FERROSFERRIC OXIDE** (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-459-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	

## SHISEIDO THE MAKEUP FOUNDATION 160

titanium dioxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-460
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

### Inactive Ingredients

Ingredient Name	Strength
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	

<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>MICA</b> (UNII: V8A1AW0880)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-460-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	

## SHISEIDO THE MAKEUP FOUNDATION B20

titanium dioxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-461
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	

<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)
<b>MICA</b> (UNII: V8A1AW0880)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-461-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	

## SHISEIDO THE MAKEUP FOUNDATION B40

titanium dioxide stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-462
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

## Inactive Ingredients

Ingredient Name	Strength
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-462-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	

## SHISEIDO THE MAKEUP FOUNDATION B60

titanium dioxide stick

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-534
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	400 mg in 10 g

### Inactive Ingredients

Ingredient Name	Strength
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>KAOLIN</b> (UNII: 24H4NWX5CO)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>SORBITAN SESQUIISOSTEARATE</b> (UNII: VU97D01BF9)	
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)	
<b>PHYTOSTERYL/OCTYLDODECYL LAUROYL GLUTAMATE</b> (UNII: 65954KGO9Q)	
<b>.ALPHA.-TOCOPHEROL ACETATE, DL-</b> (UNII: WR1WPI7EW8)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>.ALPHA.-TOCOPHEROL</b> (UNII: H4N855PNZ1)	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-534-20	1 in 1 CARTON	01/01/2018	
1		10 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 Drug	M020	01/01/2018	
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**Labeler** - SHISEIDO AMERICAS CORPORATION (193691821)

**Establishment**

Name	Address	ID/FEI	Business Operations
Shiseido America Inc.		782677132	analysis(58411-458, 58411-459, 58411-460, 58411-461, 58411-462, 58411-534) , manufacture(58411-458, 58411-459, 58411-460, 58411-461, 58411-462, 58411-534)

Revised: 1/2026

SHISEIDO AMERICAS CORPORATION