

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) B00- titanium dioxide powder

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) B100- titanium dioxide powder

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) I100- titanium dioxide powder

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) WB40- titanium dioxide powder

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) WB60- titanium dioxide powder

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 ADVANCED HYDRO-LIQUID COMPACT (REFILL)

Drug Facts

Active ingredient

TITANIUM DIOXIDE 4.5%

Purpose

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

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

Inactive Ingredients

CYCLOMETHICONE, WATER, GLYCERIN, DIMETHICONE, DIPROPYLENE GLYCOL, PARAFFIN, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, SORBITAN SESQUIISOSTEARATE, PETROLATUM, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, MICROCRYSTALLINE WAX, PEG/PPG-36/41 DIMETHYL ETHER, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL, SODIUM HYALURONATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, POLYSILICONE-2, ALUMINA, HYDROGEN DIMETHICONE, DISTEARYLDIMONIUM CHLORIDE, PALMITIC ACID, PEG-10 DIMETHICONE, ALUMINUM HYDROXIDE, BARIUM SULFATE, TOCOPHEROL, ISOPROPYL ALCOHOL, DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE, METHICONE, TITANIUM DIOXIDE, TETRADECENE, PHENOXYETHANOL, 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 - 12 g Tray Carton - B00

SHISEIDO

B00

Advanced Hydro-Liquid
Compact (Refill)
Flawless, Radiant
Coverage Foundation

BROAD SPECTRUM
SPF 15
sunscreen

12g NET WT. .42 OZ.



Advanced Hydro-Liquid Compact (Refill)

Coverage: Medium

Finish: Lustrous

Skin Type: All skin types

READ INSERTION.

VERY LIGHT BEIGE **B 00**

GLO.10799

Drug Facts
(continued)

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

SHISEIDO

B 00



Advanced Hydro-Liquid Compact (Refill)

Flawless, Radiant Coverage Foundation

BROAD SPECTRUM

SPF 15

sunscreen

12g NET WT. .42 OZ.

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Questions or Comments? Call toll free 1.800.906.7503
Drug Facts (continued)

7K194-400
JAB

Specially formulated
by Shiseido
Laboratories, Japan.

Drug Facts
(continued)

Inactive ingredients

CYCLOMETHICONE • WATER • GLYCERIN •
DIMETHICONE • DIPROPYLENE GLYCOL •
PARAFFIN •
DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER •
SORBITAN SESQUISOOSTEARATE • PETROLATUM •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
MICROCRYSTALLINE WAX •
PEG/PPG-36/41 DIMETHYL ETHER •
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL •
SODIUM HYALURONATE •
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL •
POLYSILICONE-2 • ALUMINA •
HYDROGEN DIMETHICONE •
DISTEARYLDIMONIUM CHLORIDE •
PALMITIC ACID • PEG-10 DIMETHICONE •
ALUMINUM HYDROXIDE • BARIUM SULFATE •
TOCOPHEROL • ISOPROPYL ALCOHOL •
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE •
METHICONE • TETRADECENE • PHENOXYETHANOL •
TITANIUM DIOXIDE • IRON OXIDES • MICA •

Other Information

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

SHISEIDO
ADVANCED HYDRO-LIQUID COMPACT (REFILL)

A cream-in-a-compact foundation with rich, luxurious moisture glides smoothly onto skin for a lustrous and luminous complexion. Maintains a beautiful finish all day long. Dry use only.

Drug Facts

Active ingredient	Purpose
TITANIUM DIOXIDE 4.5%	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

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

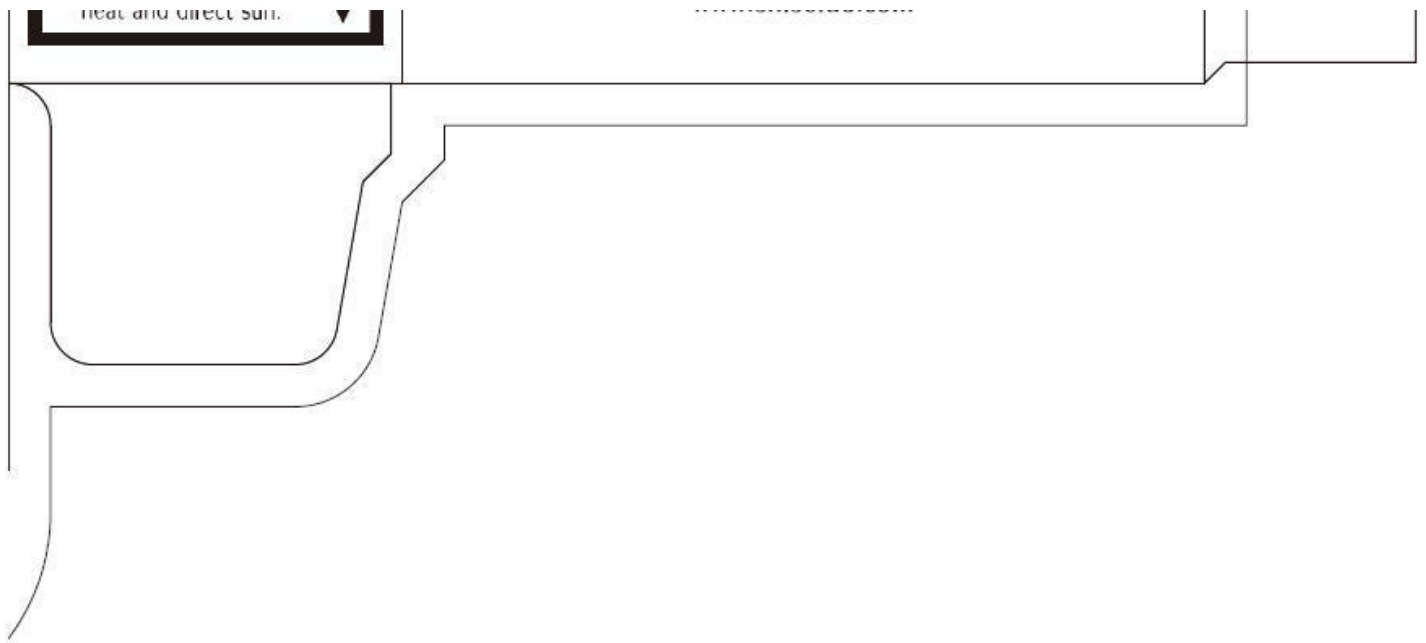
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NEW YORK, NY 10022
MADE IN U.S.A.

www.shiseido.com



57X28X76

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PRINCIPAL DISPLAY PANEL - 12 g Tray Carton - B100

SHISEIDO

B100

Advanced Hydro-Liquid
Compact (Refill)
Flawless, Radiant
Coverage Foundation

BROAD SPECTRUM
SPF 15
sunscreen

12g NET WT. .42 OZ.



Advanced Hydro-Liquid Compact (Refill)

Coverage: Medium

Finish: Lustrous

Skin Type: All skin types

READ INSERTION.

VERY DEEP BEIGE **B 100**

GLO.10800

Drug Facts
(continued)

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 ▶

SHISEIDO

B 100



Advanced Hydro-Liquid Compact (Refill)

Flawless, Radiant Coverage Foundation

BROAD SPECTRUM

SPF 15

sunscreen

12g NET WT. .42 OZ.

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Questions or Comments? Call toll free 1.800.906.7503
Drug Facts (continued)

7K195-400
JAB

Specially formulated
by Shiseido
Laboratories, Japan.

Drug Facts
(continued)

Inactive ingredients

CYCLOMETHICONE • WATER • GLYCERIN •
DIMETHICONE • DIPROPYLENE GLYCOL •
PARAFFIN •
DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER •
SORBITAN SESQUISOESTEATE • PETROLATUM •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
MICROCRYSTALLINE WAX •
PEG/PPG-36/41 DIMETHYL ETHER •
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL •
SODIUM HYALURONATE •
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL •
POLYSILICONE-2 • ALUMINA •
HYDROGEN DIMETHICONE •
DISTEARYLDIMONIUM CHLORIDE •
PALMITIC ACID • PEG-10 DIMETHICONE •
ALUMINUM HYDROXIDE • BARIUM SULFATE •
TOCOPHEROL • ISOPROPYL ALCOHOL •
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE •
METHICONE • TETRADECENE • PHENOXYETHANOL •
TITANIUM DIOXIDE • IRON OXIDES • MICA •

Other Information

■ protect this product in this
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heat and direct sun

SHISEIDO
ADVANCED HYDRO-LIQUID COMPACT (REFILL)

A cream-in-a-compact foundation with rich, luxurious moisture glides smoothly onto skin for a lustrous and luminous complexion. Maintains a beautiful finish all day long. Dry use only.

Drug Facts

Active ingredient	Purpose
TITANIUM DIOXIDE 4.5%	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

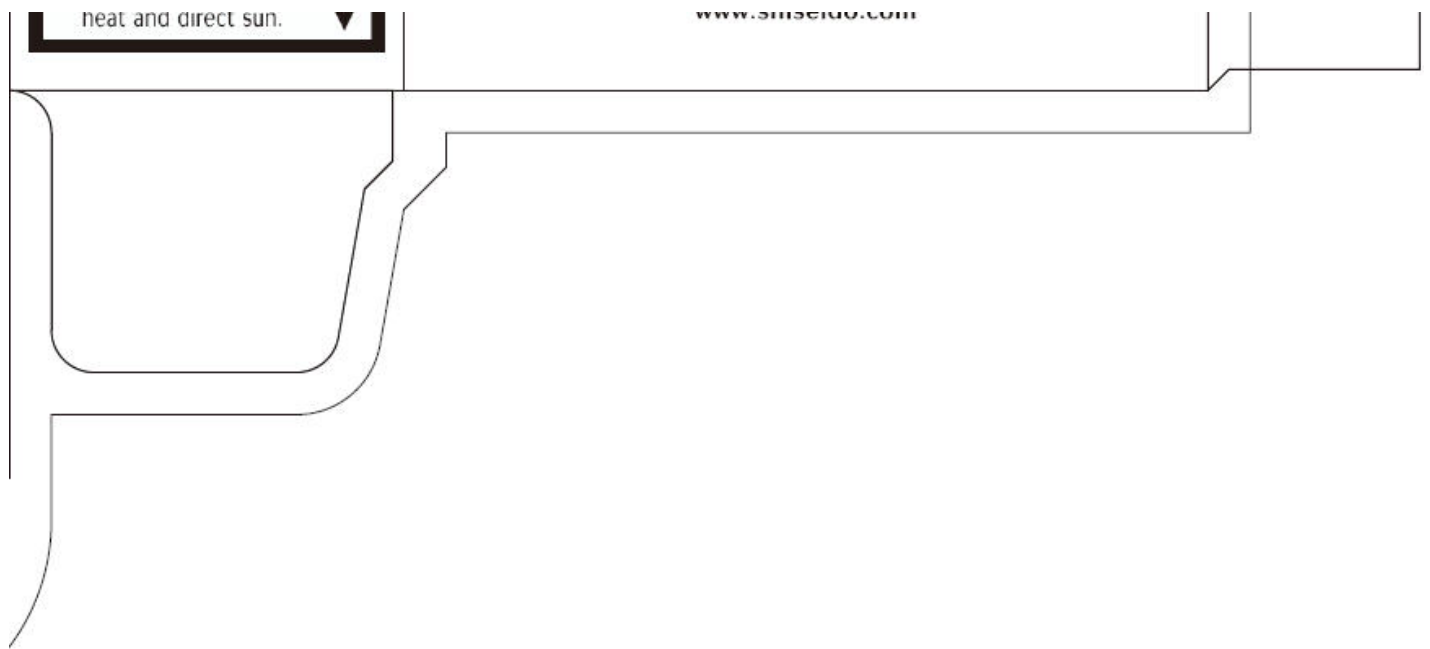
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Control Center right away. ▶

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PRINCIPAL DISPLAY PANEL - 12 g Tray Carton - I100

SHISEIDO

I100

Advanced Hydro-Liquid
Compact (Refill)
Flawless, Radiant
Coverage Foundation

BROAD SPECTRUM
SPF 15
sunscreen

12g NET WT. .42 OZ.



Advanced Hydro-Liquid Compact (Refill)

Coverage: Medium

Finish: Lustrous

Skin Type: All skin types

READ INSERTION.

VERY DEEP IVORY **1100**

GLO.10801

Drug Facts
(continued)

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 ▶

SHISEIDO

1100



Advanced Hydro-Liquid Compact (Refill)

Flawless, Radiant Coverage Foundation

BROAD SPECTRUM

SPF 15
sunscreen

12g NET WT. .42 OZ.

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Questions or Comments? Call toll free 1-800-906-7503
Drug Facts (continued)

7K196-400
JAB

Specially formulated
by Shiseido
Laboratories, Japan.

**Drug Facts
(continued)**

Inactive ingredients

CYCLOMETHICONE • WATER • GLYCERIN •
DIMETHICONE • DIPROPYLENE GLYCOL •
PARAFFIN •
DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER •
SORBITAN SESQUISOOSTEARATE • PETROLATUM •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
MICROCRYSTALLINE WAX •
PEG/PPG-36/41 DIMETHYL ETHER •
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL •
SODIUM HYALURONATE •
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL •
POLYSILICONE-2 • ALUMINA •
HYDROGEN DIMETHICONE •
DISTEARYLDIMONIUM CHLORIDE •
PALMITIC ACID • PEG-10 DIMETHICONE •
ALUMINUM HYDROXIDE • BARIUM SULFATE •
TOCOPHEROL • ISOPROPYL ALCOHOL •
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE •
METHICONE • TETRADECENE • PHENOXYETHANOL •
TITANIUM DIOXIDE • IRON OXIDES • MICA •

Other Information

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

SHISEIDO
ADVANCED HYDRO-LIQUID COMPACT (REFILL)

A cream-in-a-compact foundation with rich, luxurious moisture glides smoothly onto skin for a lustrous and luminous complexion. Maintains a beautiful finish all day long. Dry use only.

Drug Facts

Active ingredient	Purpose
TITANIUM DIOXIDE 4.5%	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

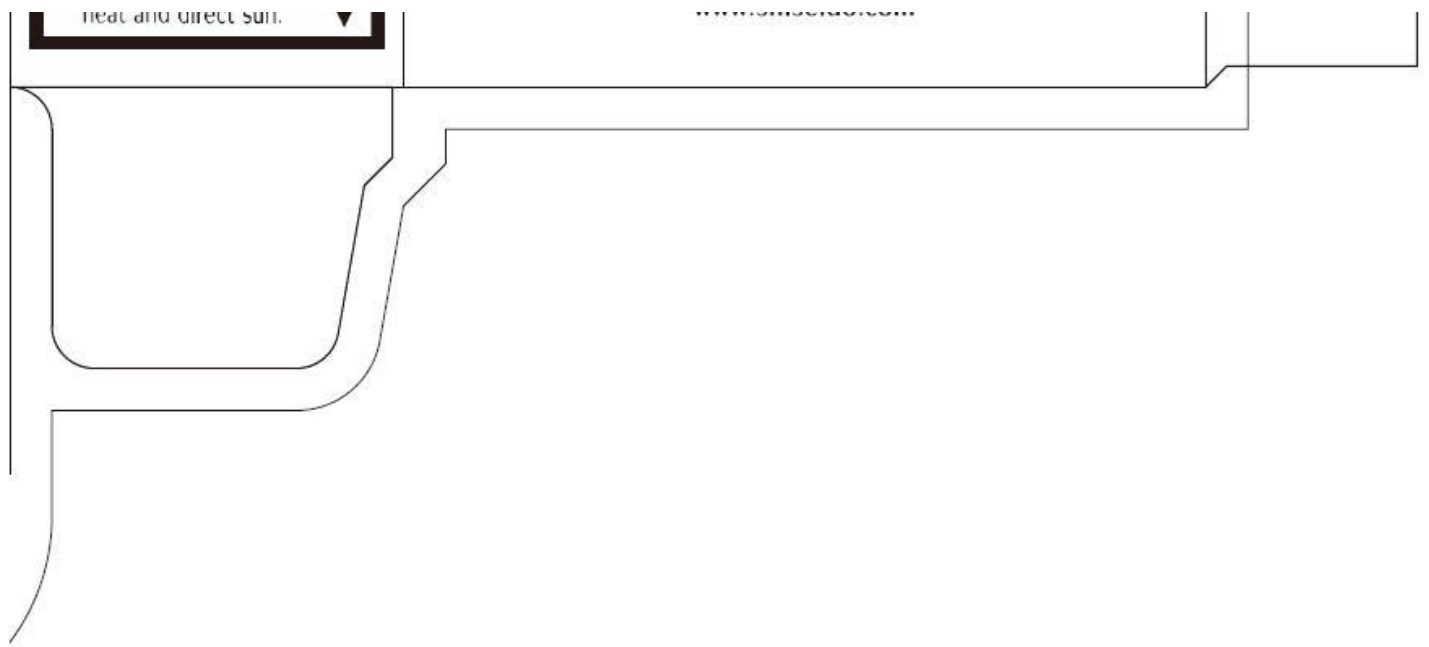
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PRINCIPAL DISPLAY PANEL - 12 g Tray Carton - WB40

SHISEIDO

WB40

Advanced Hydro-Liquid
Compact (Refill)
Flawless, Radiant
Coverage Foundation

BROAD SPECTRUM

SPF 15

sunscreen

12g NET WT. .42 OZ.



Advanced Hydro-Liquid Compact (Refill)

Coverage: Medium

Finish: Lustrous

Skin Type: All skin types

READ INSERTION.

NATURAL FAIR WARM BEIGE **WB 40**
GLO 10802

Drug Facts
(continued)

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

SHISEIDO

WB 40



Advanced Hydro-Liquid Compact (Refill)

Flawless, Radiant Coverage Foundation

BROAD SPECTRUM

SPF 15
sunscreen

12g NET WT. .42 OZ.

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Questions or Comments? Call toll free 1.800.906.7503
Drug Facts (continued)

7K197-400
JAB

Specially formulated
by Shiseido
Laboratories, Japan.

**Drug Facts
(continued)**

Inactive ingredients

CYCLOMETHICONE • WATER • GLYCERIN •
DIMETHICONE • DIPROPYLENE GLYCOL •
PARAFFIN •
DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER •
SORBITAN SESQUISOOSTEARATE • PETROLATUM •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
MICROCRYSTALLINE WAX •
PEG/PPG-36/41 DIMETHYL ETHER •
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL •
SODIUM HYALURONATE •
LAWANDULA ANGUSTIFOLIA (LAVENDER) OIL •
POLYSILICONE-2 • ALUMINA •
HYDROGEN DIMETHICONE •
DISTEARYLDIMONIUM CHLORIDE •
PALMITIC ACID • PEG-10 DIMETHICONE •
ALUMINUM HYDROXIDE • BARIUM SULFATE •
TOCOPHEROL • ISOPROPYL ALCOHOL •
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE •
METHICONE • TETRADECENE • PHENOXYETHANOL •
TITANIUM DIOXIDE • IRON OXIDES • MICA •

Other Information

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

SHISEIDO
ADVANCED HYDRO-LIQUID COMPACT (REFILL)

A cream-in-a-compact foundation with rich, luxurious moisture glides smoothly onto skin for a lustrous and luminous complexion. Maintains a beautiful finish all day long. Dry use only.

Drug Facts

Active ingredient	Purpose
TITANIUM DIOXIDE 4.5%	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

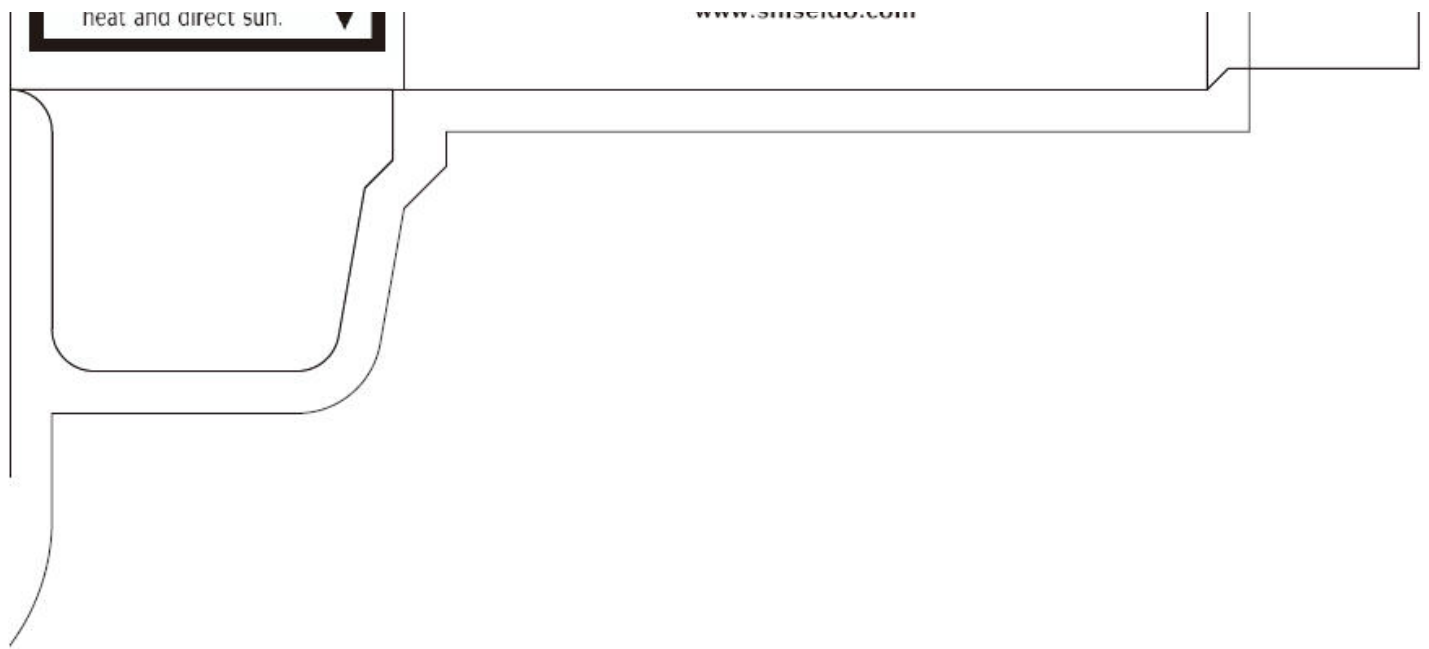
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PRINCIPAL DISPLAY PANEL - 12 g Tray Carton - WB60

SHISEIDO

WB60

Advanced Hydro-Liquid
Compact (Refill)
Flawless, Radiant
Coverage Foundation

BROAD SPECTRUM

SPF 15

sunscreen

12g NET WT. .42 OZ.



Advanced Hydro-Liquid Compact (Refill)

Coverage: Medium

Finish: Lustrous

Skin Type: All skin types

READ INSERTION.

NATURAL DEEP WARM BEIGE **WB 60**
GLO.10803

Drug Facts
(continued)

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 ▶

SHISEIDO

WB 60



Advanced Hydro-Liquid Compact (Refill)

Flawless, Radiant Coverage Foundation

BROAD SPECTRUM

SPF 15
sunscreen

12g NET WT. .42 OZ.

7 29238 10803 5

Questions or Comments? Call toll free 1-800-906-7503
Drug Facts (continued)

7K198-400
JAB

Specially formulated
by Shiseido
Laboratories, Japan.

Drug Facts
(continued)

Inactive ingredients

CYCLOMETHICONE • WATER • GLYCERIN •
DIMETHICONE • DIPROPYLENE GLYCOL •
PARAFFIN •
DIMETHICONE/VINYL DIMETHICONE
CROSSPOLYMER •
SORBITAN SESQUISOOSTEARATE • PETROLATUM •
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL
DIMETHICONE •
MICROCRYSTALLINE WAX •
PEG/PPG-36/41 DIMETHYL ETHER •
ROSMARINUS OFFICINALIS (ROSEMARY) LEAF OIL •
SODIUM HYALURONATE •
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL •
POLYSILICONE-2 • ALUMINA •
HYDROGEN DIMETHICONE •
DISTEARYLDIMONIUM CHLORIDE •
PALMITIC ACID • PEG-10 DIMETHICONE •
ALUMINUM HYDROXIDE • BARIUM SULFATE •
TOCOPHEROL • ISOPROPYL ALCOHOL •
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE •
METHICONE • TETRADECENE • PHENOXYETHANOL •
TITANIUM DIOXIDE • IRON OXIDES • MICA •

Other Information

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

SHISEIDO
ADVANCED HYDRO-LIQUID COMPACT (REFILL)

A cream-in-a-compact foundation with rich, luxurious moisture glides smoothly onto skin for a lustrous and luminous complexion. Maintains a beautiful finish all day long. Dry use only.

Drug Facts

Active ingredient	Purpose
TITANIUM DIOXIDE 4.5%	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
Keep out of reach of children. If product is
swallowed, get medical help or contact a Poison
Control Center right away. ▶

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NEW YORK, NY 10022
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heat and direct sun.

www.shiseido.com

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) B00

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-174
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	540 mg in 12 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PARAFFIN (UNII: I9O0E3H2ZE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALUMINUM OXIDE (UNII: LM26O6933)	

DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
PALMITIC ACID (UNII: 2V16EO95H1)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
BARIUM SULFATE (UNII: 25BB7EKE2E)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
METHICONE (20 CST) (UNII: 6777U11MKT)
TETRADECENE (UNII: FW23481S7S)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
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:58411-174-30	1 in 1 CARTON		
1		12 g in 1 TRAY		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2014	

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) B100
titanium dioxide powder

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	540 mg in 12 g

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

DIPROPYLENE GLYCOL (UNII: E107L85C40)
PARAFFIN (UNII: I9O0E3H2ZE)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
PETROLATUM (UNII: 4T6H12BN9U)
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)
ROSEMARY OIL (UNII: 8LGU7VM393)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
LAVENDER OIL (UNII: ZBP1YXW0H8)
ALUMINUM OXIDE (UNII: LM26O6933)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
PALMITIC ACID (UNII: 2V16EO95H1)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
BARIUM SULFATE (UNII: 25BB7EKE2E)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
METHICONE (20 CST) (UNII: 6777U11MKT)
TETRADECENE (UNII: FW23481S7S)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
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:58411-175-30	1 in 1 CARTON		
1		12 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2014	

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) I100

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-176
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	540 mg in 12 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PARAFFIN (UNII: I9O0E3H2ZE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PALMITIC ACID (UNII: 2V16EO95H1)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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:58411-176-30	1 in 1 CARTON		
1		12 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2014	

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) WB40

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-177
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	540 mg in 12 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PARAFFIN (UNII: I9O0E3H2ZE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PALMITIC ACID (UNII: 2V16EO95H1)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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:58411-177-30	1 in 1 CARTON		
1		12 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2014	

SHISEIDO ADVANCED HYDRO-LIQUID COMPACT (REFILL) WB60

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-178
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	540 mg in 12 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PARAFFIN (UNII: I9O0E3H2ZE)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PETROLATUM (UNII: 4T6H12BN9U)	
LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: 25G622K2RA)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
PALMITIC ACID (UNII: 2V16EO95HI)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
METHICONE (20 CST) (UNII: 6777U11MKT)
TETRADECENE (UNII: FW23481S7S)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
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:58411-178-30	1 in 1 CARTON		
1		12 g in 1 TRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part352	06/01/2014	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-174, 58411-175, 58411-176, 58411-177, 58411-178) , ANALYSIS(58411-174, 58411-175, 58411-176, 58411-177, 58411-178)

Establishment

Name	Address	ID/FEI	Business Operations
Davlyn Industries Inc		624436254	MANUFACTURE(58411-174, 58411-175, 58411-176, 58411-177, 58411-178)

Revised: 5/2014

SHISEIDO AMERICAS CORPORATION