

SHISEIDO PERFECT REFINING FOUNDATION D10- octinoxate and titanium dioxide cream
SHISEIDO PERFECT REFINING FOUNDATION D20- octinoxate and titanium dioxide cream
SHISEIDO PERFECT REFINING FOUNDATION D30- octinoxate and titanium dioxide cream
SHISEIDO AMERICA INC.

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 PERFECT REFINING FOUNDATION (D10, D20, D30)

Drug Facts

ACTIVE INGREDIENTS:	Purpose
OCTINOXATE 2.9%	Sunscreen
TITANIUM DIOXIDE 5.8%	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

WATER, DIMETHICONE, CYCLOMETHICONE, NYLON-12, SD ALCOHOL 40-B, DIETHYLHEXYL SUCCINATE, GLYCERIN, LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, PEG-10 DIMETHICONE, ERYTHRITOL, XYLITOL, POLYGLYCERYL-2 DIISOSTEARATE, PEG/PPG-36/41 DIMETHYL ETHER, SODIUM HYALURONATE, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, PAEONIA ALBIFLORA ROOT EXTRACT, ALUMINUM HYDROXIDE, ALUMINUM DISTEARATE, TRISODIUM EDTA,

DISTEARDIMONIUM HECTORITE, POLYSILICONE-2, VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER, BUTYLENE GLYCOL, TOCOPHEROL, DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE, BARIUM SULFATE, SODIUM METABISULFITE, BHT, METHICONE, TETRADECENE, HYDROGEN DIMETHICONE, ALUMINA, PHENOXYETHANOL, BENZOIC ACID, IRON OXIDES, ZINC OXIDE, 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

SHISEIDO AMERICA INC.
NEW YORK, N.Y. 10022

PRINCIPAL DISPLAY PANEL - 30mL D 10 Tube Carton

SHISEIDO

D 10

Perfect Refining
Foundation

All-Day Flawless,
Optimal Moisture

BROAD SPECTRUM
SPF 15
sunscreen

30mL 1 FL. OZ.



Perfect Refining Foundation
 Coverage: Medium
 Finish: Semi-matte
 Skin Type:
 Normal and Combination
 READ INSERTION.

GOLDEN BROWN **D 10**
 GLO.10874

Specially formulated
 by Shiseido
 Laboratories, Japan.

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

D 10



Perfect Refining Foundation
 All-Day Flawless,
 Optimal Moisture
 BROAD SPECTRUM
 SPF 15
 sunscreen

30mL 1FL.OZ.

Drug Facts
 (continued)

Inactive ingredients

WATER • DIMETHICONE • CYCLOMETHICONE • NYLON-12 • SD ALCOHOL 40-8 • DIETHYLHEXYL SUCINATE • GLYCERIN • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHACRYLATE • PEG-10 DIMETHICONE • ERITHRITOL • XYLITOL • POLYGLYCOLYLL-20 • ISOSTEARATE • PERPPG-3641 DIMETHYL ETHER • SODIUM HYALURONATE • LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL • PEAUNA ALBERGIA ROOT EXTRACT • ALUMINUM HYDROXIDE • ALUMINUM DISTEARATE • TRICAPRYLIN • DISTEAROYL MONOUNDECYLATE • POLYURETHANE-9 • VINYL DIMETHACRYLATE/METHACRYLATE COPOLYMER • CROSSLINKED POLYMER • BUTYLENE GLYCOL • TOCOPHEROL • DIPENTAERYTHRYL HEXANOIDYSEOSTEARATE • BARLIUM SULFATE • SODIUM METABISULFATE • DHT • METHACRYLATE • TETRADECENE • HYDROGEN DIMETHICONE • ALUMINA • PHENOLMETHANOL • BENZOIC ACID • IRON OXIDES • ZINC OXIDE • MICA • TITANIUM DIOXIDE •

Other Information

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

SHISEIDO
 PERFECT REFINING FOUNDATION

A smooth, light liquid foundation that fits seamlessly against skin, instantly erasing conspicuous pores, acne scars, and skin roughness for even, perfect coverage all day long.

Drug Facts

Active ingredients Purpose
 OCTINOXATE 2.9%.....Sunscreen
 TITANIUM DIOXIDE 5.8%...Sunscreen

Use

■ helps prevent sunburn

Warnings

For external use only

Do not use on damaged or broken skin

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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. ▶

SHISEIDO AMERICA INC.
 NEW YORK, N.Y. 10022
 MADE IN U.S.A.

www.shiseido.com



40x29x77
 1 2 3 4 5 6 7 8 9 0

7 30852 10874 5

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

10874-41-5040
 AAA

PRINCIPAL DISPLAY PANEL - 30mL D 20 Tube Carton

SHISEIDO


D 20

Perfect Refining
 Foundation

All-Day Flawless,
 Optimal Moisture

BROAD SPECTRUM

SPF 15
 sunscreen
 30mL 1 FL. OZ.

RECOMMENDED

DAILY USE

Perfect Refining Foundation
 Coverage: Medium
 Finish: Semi-matte
 Skin Type:
 Normal and Combination
 READ INSERTION.


RICH BROWN **D 20**
 G.L.O.10875

Specially formulated
 by Shiseido
 Laboratories, Japan.

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 ▶

D 20



Perfect Refining Foundation
 All-Day Flawless,
 Optimal Moisture
 BROAD SPECTRUM
 SPF 15
 sunscreen

30mL 1FL. OZ.

Drug Facts
(continued)

Inactive ingredients
 WATER • DIMETHICONE • CYCLOMETHICONE • NYLON-12 • SD ALCOHOL-40-B • DIETHYLENE GLYCOL SUCCINATE • GLYCERIN • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • PEG-10 DIMETHICONE • ERYTHRITOL • XYLITOL • POLYHYDROXY-2-ETHYL STEARATE • PEG/PPG-36/41 DIMETHYL ETHER • SODIUM HYALURONATE • LAVANDULA ANGUSTIFOLIA OIL • FACONIA ALBA ROOT EXTRACT • ALUMINUM HYDROXIDE • ALUMINUM DISTEARATE • TRICOCLUM EDTA • DISTEAROYL DIMONIUM HECOTRIATE • POLYBUTYLENE-2 • VINYL DIMETHACRYLATE/METHACRYLATE COPOLYMER • BUTYLENE GLYCOL • TOCOPHEROL • DIPENTAERYTHRYL HEXAHYDROXYSTEARATE • BARIUM SULFATE • SODIUM METABISULFATE • GHT • METHACRYLONITRILE • TETRADECENE • HYDROGEN DIMETHACRYLATE • ALLUMINA • PHENOLMETHANOL • BENZOIC ACID • IRON OXIDES • ZINC OXIDE • MICA • TITANIUM DIOXIDE •

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

SHISEIDO
 PERFECT REFINING FOUNDATION

A smooth, light liquid foundation that fits seamlessly against skin, instantly erasing conspicuous pores, acne scars, and skin roughness for even, perfect coverage all day long.

Drug Facts

Active ingredients Purpose
 OCTINOXATE 2.9%.....Sunscreen
 TITANIUM DIOXIDE 5.8%...Sunscreen

Use
 ■ helps prevent sunburn

Warnings
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Do not use on damaged or broken skin
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SHISEIDO AMERICA INC.
 NEW YORK, N.Y. 10022
 MADE IN U.S.A.
 www.shiseido.com

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

Drug Facts (continued)

10875-41-5040
 AAA

40x29x77

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PRINCIPAL DISPLAY PANEL - 30mL D 30 Tube Carton
SHISEIDO
D 30

Perfect Refining
Foundation

All-Day Flawless,
Optimal Moisture

BROAD SPECTRUM

SPF 15

sunscreen

30mL 1 FL. OZ.



Perfect Refining Foundation

Coverage: Medium
Finish: Semi-matte
Skin Type:
Normal and Combination

READ INSERTION.

VERY RICH BROWN **D 30**
GLO 10876

Specially formulated
by Shiseido
Laboratories, Japan.

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



Perfect Refining
Foundation
All-Day Flawless,
Optimal Moisture

BROAD SPECTRUM
SPF 15
sunscreen

30mL 1FL. OZ.

Drug Facts
(continued)

Inactive ingredients

WATER • DIMETHICONE • CYCLOMETHICONE • NYLON-12 • SD ALCOHOL 40-B • DIETHYLHEXYL SUCINATE • GLYCERIN • LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • PEG-10 DIMETHICONE • ERITHRITOL • XYLITOL • POLYGLYCERYL-2 STEARATE • PERPPG-26/41 DIMETHYL ETHER • SODIUM HYALURONATE • LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL • FAECIA ALBA (LILY) ROOT EXTRACT • ALUMINUM HYDROXIDE • ALUMINUM OXIDE • TITANIUM DIOXIDE • DISTEAROYL DIMONIUM HECTOATE • POLYBUTENE-2 • VINYL DIMETHACRYLATE/METHACRYLATES/SOLUBLE POLYMER • CROSSLINKED POLYMER • BUTYLENE GLYCOL • TOCOPHEROL • DIPENTAERYTHRYL HEXAHYDROXYSTEARATE • BARIUM SULFATE • SODIUM METABISULFATE • GHT • METHACRYLATE • TETRAHYDROFURAN • HYDROGEN DIMETHICONE • ALLUMINA • PHENOLMETHANOL • BENZOIC ACID • IRON OXIDES • ZINC OXIDE • MICA • TITANIUM DIOXIDE

Other Information

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

SHISEIDO
PERFECT REFINING FOUNDATION

A smooth, light liquid foundation that fits seamlessly against skin, instantly erasing conspicuous pores, acne scars, and skin roughness for even, perfect coverage all day long.

Drug Facts

Active ingredients Purpose

OCTINOXATE 2.9%.....Sunscreen
TITANIUM DIOXIDE 5.8%.....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.

SHISEIDO AMERICA INC.
NEW YORK, N.Y. 10022
MADE IN U.S.A.

www.shiseido.com



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1 2 3 4 5 6 7 8 9 0

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

Drug Facts (continued)

10876-41-5040
AAA

SHISEIDO PERFECT REFINING FOUNDATION D10

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-277
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	983 mg in 33.9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1966 mg in 33.9 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
NYLON-12 (UNII: 446U8J075B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ERYTHRITOL (UNII: RA96B954X6)	
XYLITOL (UNII: VCQ006KQ1E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
ZINC OXIDE (UNII: SOI2LOH54Z)	
MICA (UNII: V8A1AW0880)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	
ALUMINUM OXIDE (UNII: LM26O6933)	

BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-277-60	1 in 1 CARTON	02/01/2011	
1		33.9 g in 1 TUBE; 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	02/01/2011	

SHISEIDO PERFECT REFINING FOUNDATION D20

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-278
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	983 mg in 33.9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1966 mg in 33.9 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	
NYLON-12 (UNII: 446U8J075B)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ERYTHRITOL (UNII: RA96B954X6)	
XYLITOL (UNII: VCQ006KQ1E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	

HYALURONATE SODIUM (UNII: YSE9PPT4TH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ZINC OXIDE (UNII: SOI2LOH54Z)
MICA (UNII: V8A1AW0880)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
BARIUM SULFATE (UNII: 25BB7EKE2E)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
LAVENDER OIL (UNII: ZBP1YXW0H8)
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
METHICONE (20 CST) (UNII: 6777U11MKT)
TETRADECENE (UNII: FW23481S7S)
ALUMINUM OXIDE (UNII: LM26O6933)
BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-278-60	1 in 1 CARTON	02/01/2011	
1		33.9 g in 1 TUBE; 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	02/01/2011	

SHISEIDO PERFECT REFINING FOUNDATION D30

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-279
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	983 mg in 33.9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1966 mg in 33.9 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE (UNII: NMQ347994Z)	

NYLON-12 (UNII: 446U8J075B)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
DIETHYLHEXYL SUCCINATE (UNII: 69W9UMG3P8)
GLYCERIN (UNII: PDC6A3C0OX)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
ERYTHRITOL (UNII: RA96B954X6)
XYLITOL (UNII: VCQ006KQ1E)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9U)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
EDETATE TRISODIUM (UNII: 420IP921MB)
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
ZINC OXIDE (UNII: SOI2LOH54Z)
MICA (UNII: V8A1AW0880)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
BARIUM SULFATE (UNII: 25BB7EKE2E)
SODIUM METABISULFITE (UNII: 4VON5FNS3C)
LAVENDER OIL (UNII: ZBP1YXW0H8)
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
METHICONE (20 CST) (UNII: 6777U11MKT)
TETRADECENE (UNII: FW23481S7S)
ALUMINUM OXIDE (UNII: LM26O6933)
BENZOIC ACID (UNII: 8SKN0B0MIM)

Packaging

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1	NDC:52686-279-60	1 in 1 CARTON	02/01/2011	
1		33.9 g in 1 TUBE; 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	02/01/2011	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(52686-277, 52686-278, 52686-279) , analysis(52686-277, 52686-278, 52686-279)

