

**SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 1- ensulizole, octinoxate, and titanium dioxide cream**  
**SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 2- ensulizole, octinoxate, and titanium dioxide cream**  
**SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 3- ensulizole, 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.*

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**SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR**

***Drug Facts***

<b><i>ACTIVE INGREDIENTS:</i></b>	<b><i>Purpose</i></b>
ENSULIZOLE 2.0%	Sunscreen
OCTINOXATE 7.4%	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 40 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**

WATER, DIMETHICONE, SD ALCOHOL 40-B, PENTAERYTHRITYL TETRAETHYLHEXANOATE, PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE, POLYMETHYL METHACRYLATE, GLYCERIN, DIPROPYLENE GLYCOL, DISTEARDIMONIUM HECTORITE, HYDROGENATED POLYDECENE, TRIMETHYLSILOXYSILICATE, SILICA, XYLITOL, PEG-6, PEG-32, PEG/PPG-14/7 DIMETHYL ETHER, THIOTAURINE, SAXIFRAGA SARMENTOSA EXTRACT, ARGININE HCl, ONONIS SPINOSA ROOT EXTRACT, SODIUM PCA, SOPHORA ANGUSTIFOLIA ROOT EXTRACT, PPG-17, ALUMINUM HYDROXIDE, AMINOMETHYL PROPANOL, ALUMINUM DISTEARATE, ISOSTEARIC ACID, STEARIC ACID, TRISODIUM EDTA, POLYMETHYLSILSESQUIOXANE, TALC, BUTYLENE GLYCOL, ALCOHOL, ALUMINA, POLYSILICONE-2, TRIETHOXYCAPRYLYLSILANE, POLYBUTYLENE GLYCOL/PPG-9/1 COPOLYMER, BHT, SYZYGIIUM JAMBOS LEAF EXTRACT, TOCOPHEROL, PHENOXYETHANOL, FRAGRANCE, IRON OXIDES, 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

SHISEIDO DIST.  
NEW YORK • PARIS • MILANO

## **PRINCIPAL DISPLAY PANEL - 30mL Tube Carton**

**SHISEIDO**

**1**

Anti-Aging  
UV Care

**43**

Urban Environment  
Tinted UV Protector

BROAD SPECTRUM  
SPF 43

For Face  
OIL-FREE

WATER RESISTANT  
(40 MINUTES)

SUNSCREEN

30mL NET WT. 1.1OZ.

37X26X141 1 2 3 4 5 6 7 8 9 0

SHISEIDO  
URBAN ENVIRONMENT  
TINTED UV PROTECTOR  
BROAD SPECTRUM  
SPF 43  
FOR FACE

**Multi-Environment Defense.  
Multi-Faceted Skin Protection.**

A lightweight, oil-free tinted protector that defends against daily UV rays. Anti-photo aging, anti-oxidative and moisturizing effects protect and help maintain skin's beauty. Gives skin a hint of color, for a glowing, healthy-looking complexion.

- Oil-free
- Water resistant (40 minutes)
- NON-COMEDOGENIC
- DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED

**Drug Facts**

**Active ingredients Purpose**  
ENSULIZOLE 2.0% ..... Sunscreen  
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GLO. 10531  
www.shiseido.com

**Drug Facts  
(continued)**

**Directions**

- For sunscreen use:
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■ **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:
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Urban Environment  
Tinted UV Protector  
BROAD SPECTRUM SPF 43  
For Face

1

1

Anti-Aging  
UV Care

SHISEIDO



43

Urban Environment  
Tinted UV Protector

BROAD SPECTRUM  
SPF 43

For Face  
OIL-FREE

WATER RESISTANT  
(40 MINUTES)  
SUNSCREEN

**Drug Facts  
(continued)**

**Inactive ingredients**

WATER · DIMETHICONE · SD ALCOHOL 40-B · PENTAERYTHRITYL TETRAETHYLHEXANOATE · PEG-8 POLYDIMETHYLSILOXYETHYL DIMETHICONE · POLYMETHYL METHACRYLATE · GLYCERIN · PROPYLENE GLYCOL · DIBESTEARYL DIMONIUM HEXAFLUOROPHOSPHATE · HYDROGENATED POLYDECENE · TRIMETHYLSILOXYGLUCATE · SILICA · XYLITOL · PEG-6 · PEG-20 · PEG/PPG-14/7 DIMETHYL ETHER · THIOCTAURINE · SAMPANGA SARMENTOSA EXTRACT · ARGENTINE HCl · ONONIS SPINOSA ROOT EXTRACT · SODIUM PCA · SOPHORA ANGUSTIFOLIA ROOT EXTRACT · PPG-17 · ALUMINUM HYDROXIDE · AMINOMETHYL PROPANOL · ALUMINUM OBTETEARATE · ISOSTEARIC ACID · STEARIC ACID · TITANIUM DIOXIDE · POLYMETHYLSILOXODIMANE · TALC · BUTYLENE GLYCOL · ALCOHOL · ALUMINA · POLYSILOXANE-2 · TRIMETHOXYCAPRYLYLSILANE · POLYBUTYLENE GLYCOL/PPG-8/11 COPOLYMER · BHT · SYZYGIUM JAMBOS LEAF EXTRACT · TOCOPHEROL · PHENOXYETHANOL · FRAGRANCE · IRON OXIDES · TITANIUM DIOXIDE

**Other Information**

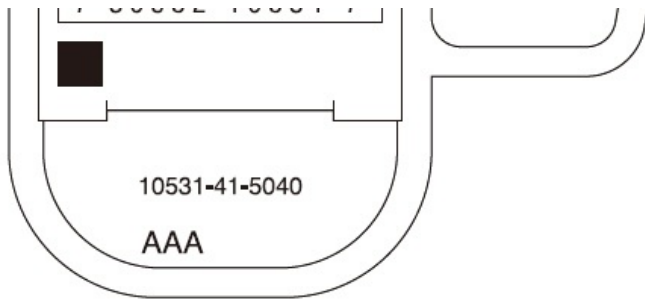
- protect this product in this container from excessive heat and direct sun.

**Questions or  
Comments?**

Call toll free  
1-800-906-7503

30mL NET WT. 1.1OZ.

7 30852 10531 7



**PRINCIPAL DISPLAY PANEL - 30mL Tube Carton**

**SHISEIDO**

**2**

Anti-Aging  
UV Care

**43**

Urban Environment  
Tinted UV Protector

**BROAD SPECTRUM**  
**SPF 43**

For Face  
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**WATER RESISTANT**  
**(40 MINUTES)**

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**30mL NET WT. 1.1OZ.**

37x26x141 1 2 3 4 5 6 7 8 9 0

SHISEIDO  
URBAN ENVIRONMENT  
TINTED UV PROTECTOR  
BROAD SPECTRUM  
SPF 43  
FOR FACE

**Multi-Environment Defense.  
Multi-Faceted Skin Protection.**

A lightweight, oil-free tinted protector that defends against daily UV rays. Anti-photo aging, anti-oxidative and moisturizing effects protect and help maintain skin's beauty. Gives skin a hint of color, for a glowing, healthy-looking complexion.

- Oil-free
- Water resistant (40 minutes)
- NON-COMEDOGENIC
- DERMATOLOGIST AND OPHTHALMOLOGIST-TESTED

**Drug Facts**

**Active ingredients Purpose**  
ENSULIZOLE 2.0% ..... Sunscreen  
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**Uses**

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[www.shiseido.com](http://www.shiseido.com)

**Drug Facts**  
(continued)

**Directions**

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■ **Sun Protection Measures.**

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BROAD SPECTRUM SPF 43  
For Face

2

2

Anti-Aging  
UV Care

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Tinted UV Protector

BROAD SPECTRUM  
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**Drug Facts**  
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**Other Information**

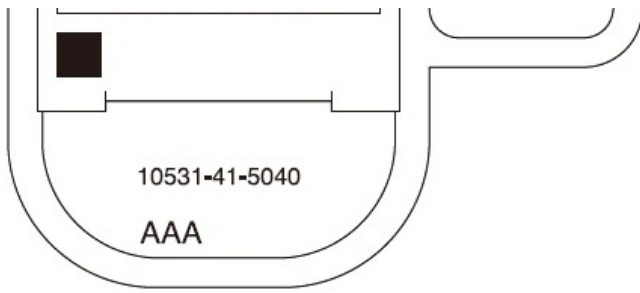
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30mL NET WT. 1.1OZ.

7 30852 10531 7



**PRINCIPAL DISPLAY PANEL - 30mL Tube Carton**

**SHISEIDO**

**3**

Anti-Aging  
UV Care

**43**

Urban Environment  
Tinted UV Protector

BROAD SPECTRUM  
SPF 43

For Face  
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SUNSCREEN

30mL NET WT. 1.1OZ.

37X26X141 1234567890

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**Drug Facts  
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3

3

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**Drug Facts  
(continued)**

**Inactive ingredients**

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**Other Information**

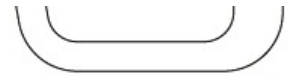
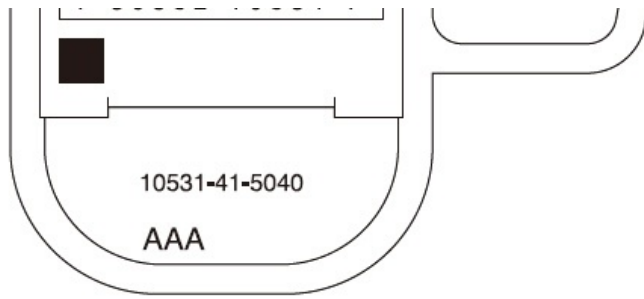
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**Questions or Comments?**

Call toll free  
1-800-906-7503

30mL NET WT. 1.1OZ.

7 30852 10531 7



## SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 1

ensulizole, octinoxate, and titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52686-339
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	656 mg in 32.79 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2426 mg in 32.79 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2361 mg in 32.79 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
THIO TAURINE (UNII: NQZ2D7AO62)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
PPG-17 (UNII: OV0Q322E0U)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UJ)	



ISOSTEARIC ACID (UNII: X33R8U0062)
STEARIC ACID (UNII: 4ELV7Z65AP)
EDETATE TRISODIUM (UNII: 420IP921MB)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
TALC (UNII: 7SEV7J4R1U)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ALCOHOL (UNII: 3K9958V90M)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-339-60	1 in 1 CARTON	03/01/2013	
1		32.79 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	03/01/2013	

## SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 2

ensulizole, octinoxate, and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-340
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ENSULIZOLE (UNII: 9YQ9DI1W42) (ENSULIZOLE - UNII:9YQ9DI1W42)	ENSULIZOLE	656 mg in 32.79 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2426 mg in 32.79 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2361 mg in 32.79 g

### Inactive Ingredients

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

PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)
GLYCERIN (UNII: PDC6A3C0OX)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
XYLITOL (UNII: VCQ006KQ1E)
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)
THIO TAURINE (UNII: NQZ2D7AO62)
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)
PPG-17 (UNII: OV0Q322E0U)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ISOSTEARIC ACID (UNII: X33R8U0062)
STEARIC ACID (UNII: 4ELV7Z65AP)
EDETATE TRISODIUM (UNII: 420IP921MB)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
TALC (UNII: 7SEV7J4R1U)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
ALCOHOL (UNII: 3K9958V90M)
ALUMINUM OXIDE (UNII: LM26O6933)
TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-340-60	1 in 1 CARTON	03/01/2013	
1		32.79 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	03/01/2013	

# SHISEIDO URBAN ENVIRONMENT TINTED UV PROTECTOR 3

ensulizole, octinoxate, and titanium dioxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52686-341
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
ENSULIZOLE (UNII: 9YQ9D11W42) (ENSULIZOLE - UNII:9YQ9D11W42)	ENSULIZOLE	656 mg in 32.79 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2426 mg in 32.79 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2361 mg in 32.79 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PENTAERYTHRITYL TETRAETHYLHEXANOATE (UNII: XJ7052W897)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
HYDROGENATED POLYDECENE (550 MW) (UNII: U333RI6EB7)	
TRIMETHYLSILOXYLSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
XYLITOL (UNII: VCQ006KQ1E)	
POLYETHYLENE GLYCOL 300 (UNII: 5655G9Y8AQ)	
POLYETHYLENE GLYCOL 1500 (UNII: 1212Z7S33A)	
PEG/PPG-14/7 DIMETHYL ETHER (UNII: 6DNW9T7YT2)	
THIO TAURINE (UNII: NQZ2D7AO62)	
SAXIFRAGA STOLONIFERA LEAF (UNII: O3TMV4903H)	
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y)	
ONONIS SPINOSA ROOT (UNII: FD2FMC53M1)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
PPG-17 (UNII: OV0Q322E0U)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)	
ISO STEARIC ACID (UNII: X33R8U0062)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
TALC (UNII: 7SEV7J4R1U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALCOHOL (UNII: 3K9958V90M)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)

SYZYGIUM JAMBOS LEAF (UNII: 407Z4W5LFF)

.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

FERRIC OXIDE RED (UNII: 1K09F3G675)

FERRIC OXIDE YELLOW (UNII: EX438O2MRT)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-341-60	1 in 1 CARTON	03/01/2013	
1		32.79 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	03/01/2013	

**Labeler** - SHISEIDO AMERICA INC. (782677132)

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-339, 52686-340, 52686-341) , ANALYSIS(52686-339, 52686-340, 52686-341)

Revised: 12/2019

SHISEIDO AMERICA INC.