

**SHISEIDO SYNCHRO SKIN TINTED 1 VERY LIGHT- octinoxate and titanium dioxide cream**  
**SHISEIDO SYNCHRO SKIN TINTED 2 LIGHT- octinoxate and titanium dioxide cream**  
**SHISEIDO SYNCHRO SKIN TINTED 3 MEDIUM- octinoxate and titanium dioxide cream**  
**SHISEIDO SYNCHRO SKIN TINTED 4 MEDIUM DARK- octinoxate and titanium dioxide cream**  
**SHISEIDO SYNCHRO SKIN TINTED 5 DARK- octinoxate and titanium dioxide cream**  
**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 SYNCHRO SKIN TINTED GEL CREAM**

**Drug Facts**

<b>Active ingredients</b>	<b>Purpose</b>
OCTINOXATE 2.9%	Sunscreen
TITANIUM DIOXIDE 6.1%	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
- 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•ISOHEXADECANE•PROPANEDIOL•ISOPROPYL MYRISTATE•TREHALOSE•ISODODECANE•ISOSTEARIC ACID•GLYCERIN•SILICA•POLYQUATERNIUM-51•THYMUS SERPYLLUM EXTRACT•SODIUM ACETYLATED HYALURONATE•CAMELLIA SINENSIS LEAF EXTRACT•METHYL METHACRYLATE/ACRYLONITRILE COPOLYMER•DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER•PEG-60 GLYCERYL ISOSTEARATE•AGAR•SORBITAN SESQUIESTEARATE•CELLULOSE GUM•ALUMINUM HYDROXIDE•POLYSILICONE-2•SODIUM CITRATE•ALCOHOL•MAGNESIUM HYDROXIDE•SUCCINOGLYCAN•BHT•BUTYLENE GLYCOL•TOCOPHEROL•CITRIC ACID•METHYL METHACRYLATE CROSSPOLYMER•SODIUM METABISULFITE•HYPERICUM ERECTUM FLOWER/LEAF/STEM EXTRACT•TALC•ALUMINA•POLYMETHYLSILSESQUIOXANE•ISOBUTANE•ISOPENTANE•PHENOXYETHANOL•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 - 40 mL Tube Carton - 1 Very Light**

**SHISEIDO**

GINZA TOKYO

**SYNCHRO SKIN**

**Tinted Gel Cream**

**Oil Free**

BROAD SPECTRUM

SPF 30

Sunscreen

40mL NET WT. 1.5 OZ.

Tinted Gel Cream



**ULTIMATE SKIN AFFINITY  
WITH RESPONSIVE SENSORY  
TECHNOLOGY.**

A revolutionary tinted gel cream that reveals a fresh, healthy complexion. Bare, but better—a truly natural, hydrated look and feel to bring out the vibrancy within.

- SHISEIDO's skincare-inspired formulation with mineral water from Kirishima, Japan.
- Protects skin from harmful factors such as UV rays, dryness, oxidants and pollution.
- Apply liberally. Reducing the quantity of application will lower the level of sunscreen protection significantly.

NON-COMEDOGENIC.  
DERMATOLOGIST-TESTED.

Formulated without:

- Oil
- Fragrance
- Parabens

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Shiseido Laboratories, Japan.

SHISEIDO AMERICAS  
CORPORATION, LEST  
NEW YORK, NY 10022  
MADE IN U.S.A.  
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**Drug Facts  
(continued)**

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<http://s1872.com/14556AA>  
See our website for more information.

**Drug Facts  
(continued)**

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WATER • ISOHEXADECANE • PROPANEDIOL • ISOPROPYL MYRISTATE • TREHALOSE • ISODODECANE • ISOSTEARIC ACID • GLYCERIN • SILICA • POLYGLUTERMINAS-1 • THYMUS SERPYLLUM EXTRACT • SODIUM ACETYLATED HYALURONATE • CAMELLIA SINENSIS LEAF EXTRACT • METHYL METHACRYLATE/ACRYLONITRILE COPOLYMER • DIMETHICONE/VINYL DIMETHICONE COPOLYMER • PEG-60 GLYCERYL ISOSTEARATE • AGAR • SORBITAN SESQUISOSEARATE • CELLULOSE GUM • ALUMINUM HYDROXIDE • POLYISODONATE-2 • SODIUM CITRATE • ALCOHOL • MAGNESIUM HYDROXIDE • SUCCOBIOGLYCAN • BHT • BUTYLENE GLYCOL • TOCOPHEROL • CITRIC ACID • METHYL METHACRYLATE COPOLYMER • SODIUM METABISULFITE • HYPERICUM ERECTUM FLOWER/LEAF/STEM EXTRACT • TALC • ALUMINA • POLYMETHYLSILOXANE • ISOBUTANE • ISOPENTANE • PHENOLMETHANOL • TITANIUM DIOXIDE • IRON OXIDES • MICA

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**SHISEIDO**  
GINZA TOKYO

**SYNCHRO SKIN**

Tinted Gel Cream

Oil Free

BROAD SPECTRUM  
SPF 30

Sunscreen

40mL NET WT. 1.5 OZ.

14556-40-5041

AAA

PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - 2 Light

SHISEIDO

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Tinted Gel Cream

Oil Free

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Specially formulated by Shiseido Laboratories, Japan.

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



**Drug Facts (continued)**

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**Drug Facts (continued)**

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**SHISEIDO**  
GINZA TOKYO

**SYNCHRO SKIN**

Tinted Gel Cream

Oil Free

BROAD SPECTRUM

SPF 30

Sunscreen

40mL NET WT. 1.5 OZ.

14556-40-5041

AAA

PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - 3 Medium

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Tinted Gel Cream

Oil Free

BROAD SPECTRUM

SPF 30

Sunscreen

40mL NET WT. 1.5 OZ.

14556-40-5041  
AAA

**PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - 4 Medium Dark**

**SHISEIDO**

GINZA TOKYO

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GINZA TOKYO

**SYNCHRO SKIN**

Tinted Gel Cream

Oil Free

BROAD SPECTRUM  
SPF 30

Sunscreen

40mL NET WT. 1.5 OZ.

14556-40-5041  
AAA

PRINCIPAL DISPLAY PANEL - 40 mL Tube Carton - 5 Dark

SHISEIDO

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**SHISEIDO SYNCHRO SKIN TINTED 1 VERY LIGHT**

octinoxate and titanium dioxide cream



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-440	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1248 mg in 40 mL	
	TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2625 mg in 40 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0KO0R)			
	ISOHEXADECANE (UNII: 918X1OUF1E)			
	PROPANEDIOL (UNII: 5965N8W85T)			
	ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)			
	TREHALOSE (UNII: B8WCK70T7I)			
	ISODOECANE (UNII: A8289P68Y2)			
	ISOSTEARIC ACID (UNII: X33R8U0062)			
	GLYCERIN (UNII: PDC6A3C0OX)			
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)			
	THYMUS SERPYLLUM (UNII: 86H4S6K51N)			
	SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)			
	GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
	DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)			
	PEG-60 GLYCERYL ISOSTEARATE (UNII: WQP0973914)			
	AGAR, UNSPECIFIED (UNII: 89T130HQ2B)			
	SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)			
	CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)			
	ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)			
	SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			
	ALCOHOL (UNII: 3K9958V90M)			
	MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)			
	BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)			
	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
	.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)			
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
	SODIUM METABISULFITE (UNII: 4VON5FNS3C)			
	HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)			
	TALC (UNII: 7SEV7J4RIU)			
	ALUMINUM OXIDE (UNII: LMI26O6933)			
	POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)			
	ISOBUTANE (UNII: BXR49TP611)			
	ISOPENTANE (UNII: ZH67814I0O)			
	PHENOXYETHANOL (UNII: HIE492ZZ3T)			
	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:58411-440-60	1 in 1 CARTON	06/01/2018	
1		40 mL 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 FINAL	part352	06/01/2018		

**SHISEIDO SYNCHRO SKIN TINTED 2 LIGHT**

octinoxate and titanium dioxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58411-441
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1248 mg in 40 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2625 mg in 40 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
WATER (UNII: 059QF0K00R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TREHALOSE (UNII: B8WCK70T7I)	
ISODODECANE (UNII: A8289P68Y2)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
THYMUS SERPYLLUM (UNII: 86H4S6K51N)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-60 GLYCERYL ISOSTEARATE (UNII: WQP0973914)	
AGAR, UNSPECIFIED (UNII: 89T130HQ2B)	
SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
ALCOHOL (UNII: 3K9958V90M)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ISOBUTANE (UNII: BXR49TP611)	
ISOPENTANE (UNII: ZH67814I0O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:58411-441-60	1 in 1 CARTON	06/01/2018	
1		40 mL 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 FINAL	part352	06/01/2018	

**SHISEIDO SYNCHRO SKIN TINTED 3 MEDIUM**

octinoxate and titanium dioxide cream

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-442
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1248 mg in 40 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2625 mg in 40 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TREHALOSE (UNII: B8WCK70T7I)	
ISODODECANE (UNII: A8289P68Y2)	
ISO STEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
THYMUS SERPYLLUM (UNII: 86H4S6K51N)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4C00W6C5)	
PEG-60 GLYCERYL ISOSTEARATE (UNII: WQP0973914)	
AGAR, UNSPECIFIED (UNII: 89T130HQ2B)	
SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
ALCOHOL (UNII: 3K9958V90M)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ISOBUTANE (UNII: BXR49TP611)	
ISOPENTANE (UNII: ZH6781410O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:58411-442-60	1 in 1 CARTON	06/01/2018
1		40 mL 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 FINAL	part352	06/01/2018	

## SHISEIDO SYNCHRO SKIN TINTED 4 MEDIUM DARK

octinoxate and titanium dioxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-443
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1248 mg in 40 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2625 mg in 40 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TREHALOSE (UNII: B8WCK70T7I)	
ISODODECANE (UNII: A8289P68Y2)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
THYMUS SERPYLLUM (UNII: 86H4S6K51N)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-60 GLYCERYL ISOSTEARATE (UNII: WQP0973914)	
AGAR, UNSPECIFIED (UNII: 89T13OHQ2B)	
SORBITAN SESQUISO STEARATE (UNII: VU97D01BF9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
ALCOHOL (UNII: 3K9958V90M)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ISOBUTANE (UNII: BXR49TP611)	
ISOPENTANE (UNII: ZH6781410O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-443-60	1 in 1 CARTON	06/01/2018	
1		40 mL 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 FINAL	part352	06/01/2018	

**SHISEIDO SYNCHRO SKIN TINTED 5 DARK**

octinoxate and titanium dioxide cream

**Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-444
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1248 mg in 40 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2625 mg in 40 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
TREHALOSE (UNII: B8WCK70T7I)	
ISODODECANE (UNII: A8289P68Y2)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
THYMUS SERPYLLUM (UNII: 86H4S6K51N)	
SODIUM ACETYLATED HYALURONATE (UNII: WN66R7GL93)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-60 GLYCERYL ISOSTEARATE (UNII: WQP0973914)	
AGAR, UNSPECIFIED (UNII: 89T130HQ2B)	
SORBITAN SESQUISOSTEARATE (UNII: VU97D01BF9)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
ALCOHOL (UNII: 3K9958V90M)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
ISOBUTANE (UNII: BXR49TP611)	



ISOPENTANE (UNII: ZH6781410O)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-444-60	1 in 1 CARTON	06/01/2018	
1		40 mL 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 FINAL	part352	06/01/2018	

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

### Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(58411-440, 58411-441, 58411-442, 58411-443, 58411-444), ANALYSIS(58411-440, 58411-441, 58411-442, 58411-443, 58411-444)

Revised: 5/2018

SHISEIDO AMERICAS CORPORATION