

**SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION NEUTRAL 5-
octinoxate and titanium dioxide emulsion
SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION ROSE 5- octinoxate
and titanium dioxide emulsion
SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION GOLDEN 5-
octinoxate and titanium dioxide emulsion
SHISEIDO AMERICAS CORPORATION**

SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
OCTINOXATE 2.9 %	Sunscreen
TITANIUM DIOXIDE 2.4 %	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.

Flammable; Do not use near heat, flame or open fire.

Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply at least every two 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

DIMETHICONE • WATER • TRIFLUOROPROPYLDIMETHYL/TRIMETHYLSILOXYSILICATE • CAPRYLIC/CAPRIC TRIGLYCERIDE • DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER • PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE • SD ALCOHOL 40-B • MAGNESIUM

MYRISTATE•NYLON-12•DIPHENYL DIMETHICONE/VINYL DIPHENYL
DIMETHICONE/SILSESQUIOXANE CROSSPOLYMER•DISTEARDIMONIUM
HECTORITE•POLYQUATERNIUM-51•THYMUS SERPILLUM EXTRACT•ALUMINUM
HYDROXIDE•ALUMINUM DISTEARATE•POLYSILICONE-
2•GLYCERIN•BHT•ALCOHOL•BUTYLENE GLYCOL•TOCOPHEROL•METHYL
METHACRYLATE CROSSPOLYMER•HYPERICUM ERECTUM FLOWER/LEAF/STEM
EXTRACT•TALC•DIMETHICONE/PEG-10/15
CROSSPOLYMER•SILICA•ALUMINA•POLYMETHYLSILSESQUIOXANE•DIISOSTEARYL
MALATE•GLYCERYL DIISOSTEARATE•DIPROPYLENE
GLYCOL•PHENOXYETHANOL•FRAGRANCE•TITANIUM DIOXIDE•IRON
OXIDES•MICA•RED 27•

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 - 30 mL Bottle Carton - Neutral 5

SHISEIDO

GINZA TOKYO

SYNCHRO SKIN

Lasting

Liquid Foundation

Oil Free

BROAD SPECTRUM

SPF 20

Sunscreen

30mL 1 FL. OZ.

Lasting Liquid Foundation



ULTIMATE SKIN AFFINITY. A NEW RESPONSIVE SENSORY TECHNOLOGY.

An intelligent, long-lasting foundation that beautifully enhances your complexion with vibrance. Flawlessly undetectable. Like it belongs to your skin.

Drug Facts

Active ingredients Purpose
OCINOXATE 3.9% Sunscreen
TITANIUM DIOXIDE 3.3% ... 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 ▶

Drug Facts (continued)

Warnings

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Flammable: Do not use near heat, flame or while smoking.

Directions

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- reapply at least every 2 hours
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 - limit time in the sun, especially from 10 a.m. - 2 p.m.
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- children under 6 months: Ask a doctor ▶

Drug Facts (continued)

Inactive ingredients

DIMETHICONE - WATER - TRIFLUOROPROPYLDIMETHYL/TRIMETHYLSILOXYSILICATE - CAPRYLIC/CAPRIC TRIGLYCERIDE - DIMETHICONE/VINYL DIMETHICONE COPOLYMER - PEG-8 POLYDIMETHYLSILOXYETHYL DIMETHICONE - SD ALCOHOL 40-B - MAGNESIUM MYRISTATE - NYLON-12 - DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE/SILSESQUOXANE COPOLYMER - POLYQUATERNIUM-51 - THYMUS SERPILLUM EXTRACT - DISTEARDIMONIUM HECTORITE - ALUMINUM HYDROXIDE - ALUMINUM DISTEARATE - POLYSILICONE-2 - GLYCERIN - BHT - ALCOHOL - BUTYLENE GLYCOL - TOCOPHEROL - METHYL METHACRYLATE COPOLYMER - HYPERICUM ERECTUM FLOWER/LEAF/STEM EXTRACT - TALC - DIMETHICONE/PEG-10/15 COPOLYMER - SILICA - ALUMINA - POLYMETHYLSILSESQUOXANE - DIISOSTEARYL MALATE - GLYCERYL DIISOSTEARATE - DIPROPYLENE GLYCOL - PHENOXYETHANOL - FRAGRANCE - IRON OXIDES - TITANIUM DIOXIDE - MICA - RED 27 -

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SHISEIDO
GINZA TOKYO

SYNCHRO SKIN

Lasting Liquid Foundation

Oil Free

BROAD SPECTRUM
SPF 20

Sunscreen

30mL 1 FL. OZ.

Specially formulated by
Shiseido Laboratories, Japan.

SHISEIDO AMERICAS
CORPORATION, 1151
NEW YORK, NY 10022
MADE IN U.S.A.
www.shiseido.com

13123-40-5040

AAA

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton - Rose 5

SHISEIDO
GINZA TOKYO

SYNCHRO SKIN

Lasting
Liquid Foundation

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SPF 20

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 - limit time in the sun, especially from 10 a.m. - 2 p.m.
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Drug Facts (continued)

Inactive ingredients

DIMETHICONE - WATER - TRIFLUOROPROPYLDIMETHYL/TRIMETHYLSILOXYSILICATE - CAPRYLIC/CAPRIC TRIGLYCERIDE - DIMETHICONE/VINYL DIMETHICONE COPOLYMER - PEG-8 POLYDIMETHYLSILOXYETHYL DIMETHICONE - SD ALCOHOL 40-B - MAGNESIUM MYRISTATE - NYLON-12 - DIPHENYL DIMETHICONE/VINYL DIPHENYL DIMETHICONE/SILSESQUOXANE COPOLYMER - POLYQUATERNIUM-51 - THYMUS SERPILLUM EXTRACT - DISTEARDIMONIUM HECTORITE - ALUMINUM HYDROXIDE - ALUMINUM DISTEARATE - POLYSILICONE-2 - GLYCERIN - BHT - ALCOHOL - BUTYLENE GLYCOL - TOCOPHEROL - METHYL METHACRYLATE COPOLYMER - HYPERICUM ERECTUM FLOWER/LEAF/STEM EXTRACT - TALC - DIMETHICONE/PEG-10/15 COPOLYMER - SILICA - ALUMINA - POLYMETHYLSILSESQUOXANE - DIOSTEARYL MALATE - GLYCERYL DIOSTEARATE - DIPROPYLENE GLYCOL - PHENOXYETHANOL - FRAGRANCE - IRON OXIDES - TITANIUM DIOXIDE - MICA - RED 27

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Questions or Comments?

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READ INSERTION.



SHISEIDO
GINZA TOKYO

SYNCHRO SKIN

Lasting Liquid Foundation

Oil Free

BROAD SPECTRUM SPF 20

Sunscreen

30mL 1 FL. OZ.

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION, 151 NEW YORK, NY 10022 MADE IN U.S.A. www.shiseido.com

13123-40-5040

AAA

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton - Golden 5

SHISEIDO
GINZA TOKYO

SYNCHRO SKIN

Lasting
Liquid Foundation

Oil Free

BROAD SPECTRUM
SPF 20

Sunscreen

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Drug Facts (continued)

Inactive ingredients

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Other Information

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Questions or Comments?

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READ INSERTION.



SHISEIDO
GINZA TOKYO

SYNCHRO SKIN

Lasting Liquid Foundation

Oil Free

BROAD SPECTRUM SPF 20

Sunscreen

30mL 1 FL. OZ.

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO AMERICAS CORPORATION, 11ST NEW YORK, NY 10022 MADE IN U.S.A. www.shiseido.com

13123-40-5040

AAA

SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION NEUTRAL 5

octinoxate and titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-624
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.31 g in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.09 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
MAGNESIUM MYRISTATE (UNII: Z1917F0578)	
NYLON-12 (UNII: 446U8J075B)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
GLYCERIN (UNII: PDC6A3C00X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)	
THYMUS SERPYLLUM WHOLE (UNII: 86H4S6K51N)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HYPERICUM ERECTUM FLOWERING TOP (UNII: IT0296HQDC)	
TALC (UNII: 7SEV7J4R1U)	
MICA (UNII: V8A1AW0880)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
GLYCERYL DIISOSTEARATE (UNII: 68BAV42LRC)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-624-10	1 in 1 CARTON	01/01/2021	
1		30 mL in 1 BOTTLE; 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	01/01/2021	

SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION ROSE 5

octinoxate and titanium dioxide emulsion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-625
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.31 g in 30 mL	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	1.09 g in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O)		
WATER (UNII: 059QF0K00R)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)		
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
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MAGNESIUM MYRISTATE (UNII: Z1917F0578)		
NYLON-12 (UNII: 446U8J075B)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
GLYCERIN (UNII: PDC6A3C00X)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
ALCOHOL (UNII: 3K9958V90M)		
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)		
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METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)		
POLYQUATERNIUM-51 (2-METHACRYLOYLOXYETHYL PHOSPHORYLCHOLINE/N-BUTYL METHACRYLATE; 3:7) (UNII: EL9825H96J)		
THYMUS SERPYLLUM WHOLE (UNII: 86H4S6K51N)		
PHENOXYETHANOL (UNII: HIE492Z3T)		

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GLYCERYL DIISOSTEARATE (UNII: 68BAV42LRC)
DIPROPYLENE GLYCOL (UNII: E107L85C40)

Packaging

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OTC Monograph Drug	M020	01/01/2021	

SHISEIDO SYNCHRO SKIN LASTING LIQUID FOUNDATION GOLDEN 5

octinoxate and titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-626
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.31 g in 30 mL
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DIPROPYLENE GLYCOL (UNII: E107L85C40)

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Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Establishment

Name	Address	ID/FEI	Business Operations
Shiseido America Inc.		782677132	analysis(58411-624, 58411-625, 58411-626) , manufacture(58411-624, 58411-625, 58411-626)