

**SHISEIDO MAKEUP REFINING MAKEUP PRIMER- 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 REFINING MAKEUP PRIMER

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
OCTINOXATE 4.9%	Sunscreen
TITANIUM DIOXIDE 7.5%	Sunscreen

Uses

- helps prevent sunburn
- -higher SPF gives more sunburn protection

Warnings

For external use only.

When using this product

- keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

- rash or irritation develops and lasts.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply evenly before sun exposure and as needed.
- children under 6 months of age: ask a doctor.

Inactive Ingredient List

CYCLOMETHICONE, WATER, DIPROPYLENE GLYCOL, SILICA, GLYCERIN, POLYMETHYLSILSESQUIOXANE, POLYMETHYL METHACRYLATE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, PEG-10 DIMETHICONE, DISTEARDIMONIUM HECTORITE, TRIMETHYLSILOXYSILICATE, PEG/PPG-36/41 DIMETHYL ETHER, LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL, ALUMINUM DISTEARATE, ALUMINUM HYDROXIDE, ISOSTEARIC ACID, TRISODIUM EDTA, DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE, POLYSILICONE-2, BHT, TOCOPHEROL, METHICONE, TETRADECENE, PHENOXYETHANOL, IRON OXIDES, MICA

Questions?

1-800-906-7503

PRINCIPAL DISPLAY PANEL - 30 mL Carton

SHI SEIDO

Refining
Makeup Primer

SPF 21
sunscreen

30mL
NET WT. 1.1OZ.

Refining Makeup Primer

GLO. 10511

SHISEIDO
REFINING
MAKEUP PRIMER
SPF 21

A refining makeup primer that minimizes the appearance of uneven skin tone, conspicuous pores and fine lines for an all-day luminous, natural-looking finish.

- NON-COMEDOGENIC.
- DERMATOLOGIST-TESTED.

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

www.shiseido.com

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Drug Facts (continued)

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SHISEIDO



Refining
Makeup Primer
SPF 21
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30mL
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Drug Facts (continued)

Inactive ingredients

CYCLOMETHICONE - WATER -
DIPROPYLENE GLYCOL - SILICA - GLYCERIN - POLYMETHYLSILSESQUOXANE -
POLYMETHYL METHACRYLATE - DIMETHICONE/METHYL DIMETHICONE CROSSPOLYMER - PEG-10 DIMETHICONE - DISTEARDIMONIUM HECTORITE - TRIMETHYLSILOXYMETHYL-
PEG/PPG-38/41 DIMETHYL ETHER -
LAVANDULA ANGUSTIFOLIA (LAVENDER) OIL - ALUMINUM DISTEARATE - ALUMINUM HYDROXIDE - ISOSTEARIC ACID - TRISODIUM EDTA - DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE - POLYSILOXANE-2 - BHT - TOCOPHEROL -
METHICONE - TETRADECENE - PHENOXYETHANOL - IRON OXIDES - MICA

Questions? 1-800-906-7503

READ INSERTION.

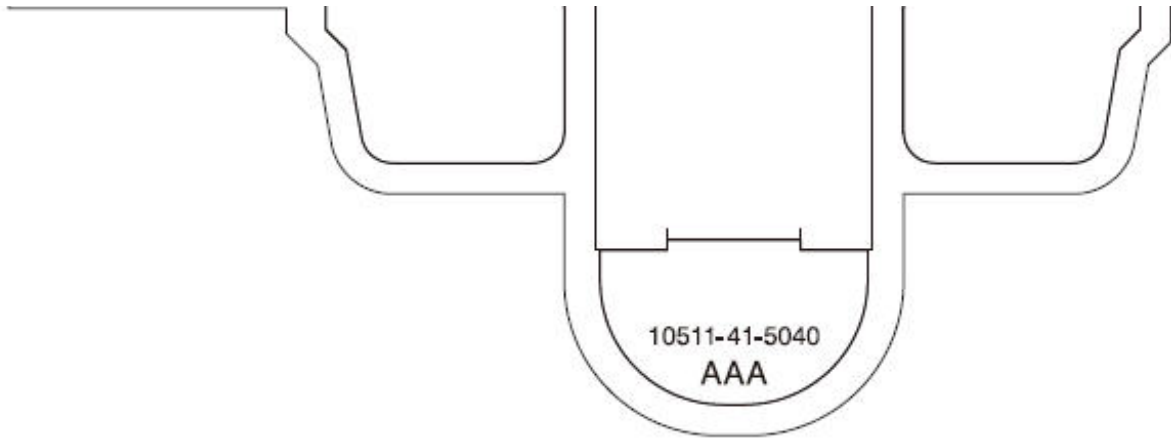
Specialy formulated by Shiseido Laboratories, Japan.

27x27x142.5

1 2 3 4 5 6 7 8 9 0

標準サイズ1.0oz 8mm×15mm×37.5mm

7 30852 10511 9



SHISEIDO MAKEUP REFINING MAKEUP PRIMER

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-229
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.528016 g in 31.184 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.3388 g in 31.184 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYMETHYLSILSESQUOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ISO STEARIC ACID (UNII: X33R8U0062)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MICA (UNII: V8A1AW0880)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-229-60	1 in 1 CARTON	09/01/2010	
1		31.184 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	09/01/2010	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(52686-229) , analysis(52686-229)

Revised: 12/2018

SHISEIDO AMERICA INC.