

SHISEIDO 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 7.4%	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.

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

CYCLOMETHICONE, WATER, DIPROPYLENE GLYCOL , SILICA , GLYCERIN , POLYMETHYLSILSESQUOXANE , 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, 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 Tube Carton

SHISEIDO

Refining
Makeup Primer

BROAD SPECTRUM
SPF 21
sunscreen

30mL
NET WT. 1.1 OZ.

27x27x142.5

1 2 3 4 5 6 7 8 9 0



SHISEIDO
REFINING
MAKEUP PRIMER
BROAD SPECTRUM
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.

Drug Facts

Active ingredients Purpose

OCTINOXATE 4.9%
..... Sunscreen
TITANIUM DIOXIDE 7.4%
..... 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 ▶

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

www.shiseido.com



Drug Facts
(continued)

Warnings

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 ▶

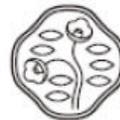
標準サイズ1.0倍 8mm/パ
15mmX37.5mm

30852 10511 9

Refining Makeup Primer

GLO. 10511

SHISEIDO



Refining
Makeup Primer
BROAD SPECTRUM
SPF 21
sunscreen

Drug Facts
(continued)

Directions

- children under 6 months: Ask a doctor

Inactive ingredients

CYCLOMETHICONE - WATER -
DIPROPYLENE GLYCOL -
SILICA - GLYCERIN -
POLYMETHYLSILSESQUOXANE -
POLYMETHYL
METHACRYLATE -
DIMETHICONE/MINYL
DIMETHICONE
CROSSPOLYMER -
PEG-10 DIMETHICONE -
DISTEAROYLMONIUM
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 -
TITANIUM DIOXIDE -

Other Information

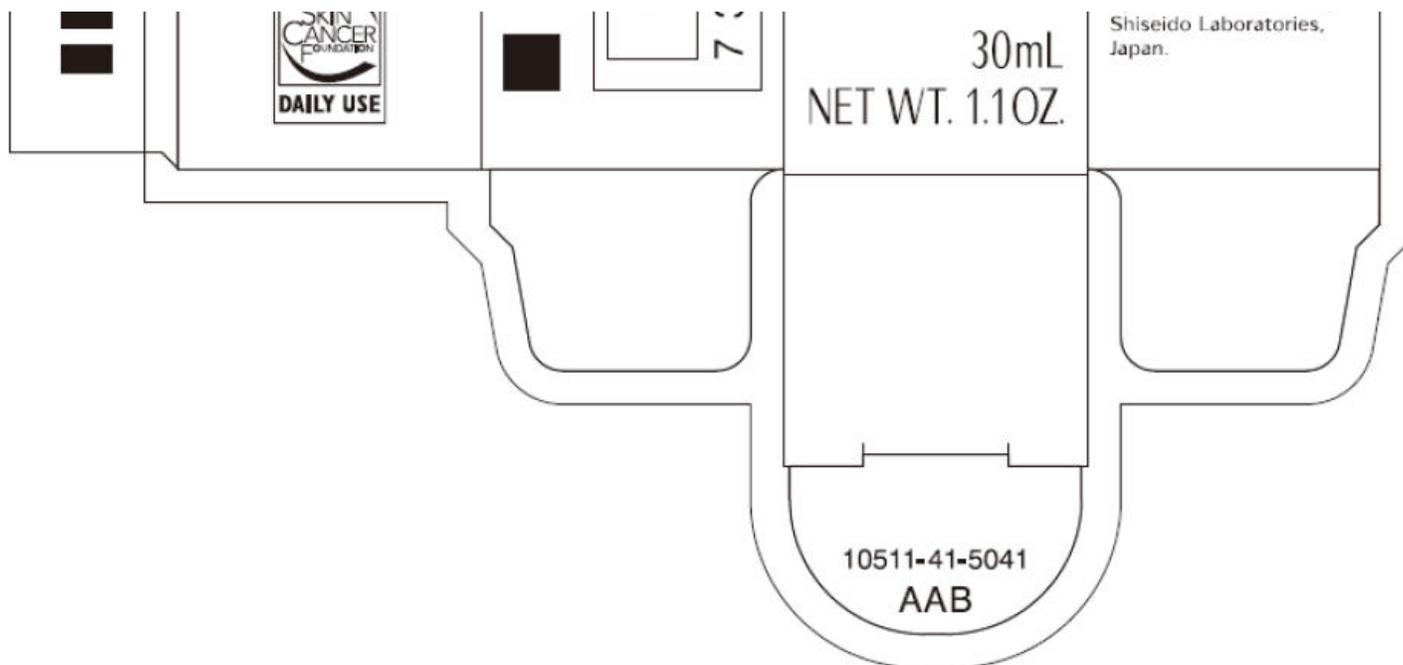
- protect this product in this container from excessive heat and direct sun.

Questions or Comments?

Call toll free
1-800-906-7503

READ INSERTION.

Specially formulated by



SHISEIDO REFINING MAKEUP PRIMER

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52686-276
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	166.1 mg in 33.9 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2509 mg in 33.9 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)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALUMINUM DISTEARATE (UNII: 7P1HP1B9UT)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

MICA (UNII: V8A1AW0880)	
EDETATE TRISODIUM (UNII: 420IP921MB)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
TOCOPHEROL (UNII: R0ZB2556P8)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
TETRADECENE (UNII: FW23481S7S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52686-276-60	1 in 1 CARTON	09/01/2010	
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	09/01/2010	

Labeler - SHISEIDO AMERICA INC. (782677132)

Establishment

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	MANUFACTURE(52686-276) , ANALYSIS(52686-276)

Revised: 12/2019

SHISEIDO AMERICA INC.