

SHISEIDO REFINING MAKEUP PRIMER- octinoxate and titanium dioxide emulsion
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.

SHISEIDO REFINING MAKEUP PRIMER

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.

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 every before sun exposure and as needed
- children under 6 months: Ask a doctor
- reapply at least every two hour

Inactive Ingredients

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 • TITANIUM DIOXIDE

Questions or comments?

Call toll free 1-800-906-7503

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

SHISEIDO

Refining
Makeup Primer

SPF 21
sunscreen

30mL
NET WT. 1.1 OZ.

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

Drug Facts

Active ingredients Purpose

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.

Drug Facts
(continued)

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.

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Drug Facts
(continued)

Inactive ingredients

CYCLOMETHICONE · WATER · DIPROPYLENE GLYCOL · SILICA · GLYCERIN · POLYMETHYLSILSESQUOXANE · POLYMETHYL METHACRYLATE · DIMETHICONE/VINYL DIMETHICONE · CROSSPOLYMER · PEG-10 DIMETHICONE · DISTEARDIMONIUM HECTORITE · TRIMETHYLSILOXYSI-LICATE · 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

READ INSERTION.
Specially formulated by Shiseido Laboratories, Japan.



Refining
Makeup Primer
SPF 21
sunscreen



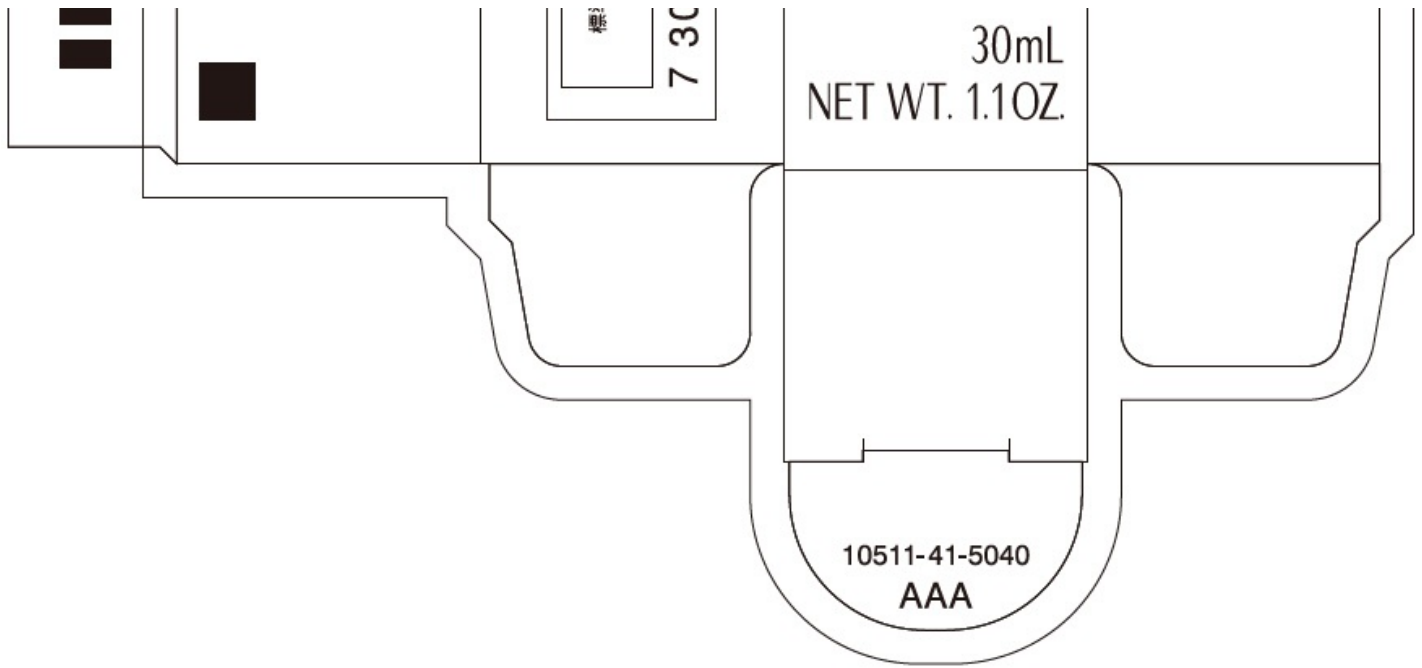
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852 10511 9

27X27X142.5

1 2 3 4 5 6 7 8 9 0





SHISEIDO REFINING MAKEUP PRIMER

octinoxate and titanium dioxide emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-630
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.69 g in 30 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2.53 g in 30 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE (UNII: NMQ347994Z)	
WATER (UNII: 059QF0KO0R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

ALUMINUM DISTEARATE (UNII: 7P1HP1B9UI)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ISOSTEARIC ACID (UNII: X33R8U0062)
EDETATE TRISODIUM (UNII: 420IP921MB)
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)
METHICONE (20 CST) (UNII: 6777U11MKT)
1-TETRADECENE (UNII: FW23481S7S)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSOFERRIC OXIDE (UNII: XM0M87F357)
MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58411-630-10	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 FINAL	part352	01/01/2021	

Labeler - SHISEIDO AMERICAS CORPORATION (193691821)

Revised: 2/2021

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