

SHISEIDO GLOW ENHANCING PRIMER- avobenzene, octinoxate, octocrylene, and oxybenzone 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.

SHISEIDO GLOW ENHANCING PRIMER

CREAM

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
AVOBENZONE 2.5%	Sunscreen
OCTINOXATE 7.4%	Sunscreen
OCTOCRYLENE 3.0%	Sunscreen
OXYBENZONE 1.0%	Sunscreen

Uses

- helps prevent sunburn

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•CETYL ETHYLHEXANOATE•GLYCERIN•BUTYLENE GLYCOL•CELLULOSE•DIMETHICONE•PEG-8•SD ALCOHOL 40-B•CAPRYLYL METHICONE•DIPROPYLENE GLYCOL•PEG-60 HYDROGENATED CASTOR OIL•PEG/PPG-

36/41 DIMETHYL ETHER•XANTHAN GUM•GLYCYL GLYCINE•PAEONIA ALBIFLORA ROOT
EXTRACT•ZINGIBER AROMATICUS EXTRACT•PPG-17•BARIUM
SULFATE•TRIETHANOLAMINE•CARBOMER•ALCOHOL•ACRYLATES/C10-30 ALKYL
ACRYLATE CROSSPOLYMER•SODIUM METAPHOSPHATE•DIPENTAERYTHRITYL
HEXAHYDROXYSTEARATE•BHT•ALUMINA•SODIUM
METABISULFITE•TOCOPHEROL•BENZOIC ACID•FRAGRANCE•MICA•TITANIUM
DIOXIDE•IRON OXIDES•

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 Tube Carton

SHISEIDO

Glow Enhancing
Primer

Smooths on for
a vibrant finish.
Oil-free.

BROAD SPECTRUM
SPF 15
sunscreen

30mL NET WT. 1 OZ.



Glow Enhancing Primer

GLO-11601

Specially formulated by Shiseido Laboratories, Japan.

SHISEIDO



Glow Enhancing Primer
Smooths on for a vibrant finish.
Oil-free.

BROAD SPECTRUM
SPF 15
sunscreen

30mL NET WT. 1OZ.

7 30852 11601 6

16mm x 33mm 10mm x 7mm
小サイズ0.85倍

11601-41-5040
AAA

Drug Facts
(continued)

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Drug Facts
(continued)

Inactive ingredients

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Questions or Comments?

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SHISEIDO
GLOW ENHANCING PRIMER

A primer that enhances skin's clarity, for a brilliant quality that adds a natural, vibrant glow to the finish of various foundations all day long.

Drug Facts

Active ingredients Purpose

AVOBENZONE 2.5% Sunscreen
OCTINOXATE 7.4% Sunscreen
OCTOCRYLENE 3.0% ... Sunscreen
OXYBENZONE 1.0% Sunscreen

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

www.shiseido.com

SHISEIDO GLOW ENHANCING PRIMER

avobenzone, octinoxate, octocrylene, and oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58411-239
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	773 mg in 30 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2287 mg in 30 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	927 mg in 30 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	309 mg in 30 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CETYL ETHYLHEXANOATE (UNII: 134647WMX4)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
.ALPHA.-CELLULOSE (UNII: B55QGZ19A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PEG-60 HYDROGENATED CASTOR OIL (UNII: 02NG325BQG)	
PEG/PPG-36/41 DIMETHYL ETHER (UNII: GZ406N3R9F)	
XANTHAN GUM (UNII: TTV12P4NEE)	
DIGLYCINE (UNII: 10525P22U0)	
PAEONIA LACTIFLORA ROOT (UNII: 3Z3866YW6P)	
PPG-17 (UNII: OV0Q322E0U)	
BARIUM SULFATE (UNII: 25BB7EKE2E)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALCOHOL (UNII: 3K9958V90M)	
SODIUM POLYMETAPHOSPHATE (UNII: P1BM4ZH95L)	
DIPENTAERYTHRITYL HEXAHYDROXYSTEARATE (UNII: 74J1X57U42)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALUMINUM OXIDE (UNII: LM26O6933)	
SODIUM METABISULFITE (UNII: 4VON5FNS3C)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
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:58411-239-60	1 in 1 CARTON	02/01/2015	
1		30 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 not final	part352	02/01/2015	

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

Name	Address	ID/FEI	Business Operations
SHISEIDO AMERICA INC.		782677132	manufacture(58411-239) , analysis(58411-239)

Revised: 12/2018

SHISEIDO AMERICAS CORPORATION