

**GIORGIO ARMANI ARMANIPRIMA COLOR CONTROL GLOW MOISTURIZER BROAD SPECTRUM SPF 35 SUNSCREEN- octinoxate and titanium dioxide lotion**  
**-L'Oreal USA Products 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.*

-----

**Drug Facts**

**Active ingredients**

Octinoxate 5%

Titanium dioxide 1.9%

**Purpose**

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

**Flammable until dry.**

Do not use near fire, flame or heat.

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

**Directions**

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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 value 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-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months of age: Ask a doctor

### **Other information**

protect the product in this container from excessive heat and direct sun

### **Inactive ingredients**

water, dimethicone, glycerin, alcohol denat., isododecane, PEG-10 dimethicone, dipropylene glycol, pentylene glycol, disteardimonium hectorite, betaine, talc, diisostearyl malate, fragrance, tocopheryl acetate, macadamia ternifolia seed oil, phenoxyethanol, adenosine, magnesium sulfate, magnesium aspartate, ethylhexyl hydroxystearate, ethyl menthane carboxamide, silica, dimethiconol, dimethicone/vinyl dimethicone crosspolymer, simmondsia chinensis (jojoba) seed oil, limonene, zinc gluconate, linalool, benzyl alcohol, copper glyconate, coriandrum sativum (coriander) fruit oil, moringa pterygosperma seed extract, passiflora edulis seed oil, disodium stearyl glutamate, methicone, prunus armeniaca (apricot) kernel oil, aluminum starch octenylsuccinate, alumina, aluminum hydroxide; may contain: red 28 lake, red 7, iron oxides, bismuth oxychloride, titanium dioxide

## Drug Facts

### Active ingredients Purpose

Octinoxate 5% ..... Sunscreen  
Titanium dioxide 1.9% .... 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

**Flammable until dry.** Do not use near fire, flame or heat.

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

### Directions

For sunscreen use:

- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 value 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-sleeved shirts, pants, hats, and sunglasses
  - children under 6 months of age: Ask a doctor

### Other information

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

### Drug Facts (continued)

#### Inactive ingredients

water, dimethicone, glycerin, alcohol denat., isododecane, PEG-10 dimethicone, dipropylene glycol, pentylene glycol, disteardimonium hectorite, betaine, tab, diisostearyl malate, fragrance, tocopheryl acetate, macadamia ternifolia seed oil, phenoxyethanol, adenosine, magnesium sulfate, magnesium aspartate, ethylhexyl hydroxystearate, ethyl menthane carboxamide, silica, dimethiconol, dimethicone/vinyl dimethicone crosspolymer, simmondsia chinensis (jojoba) seed oil, limonene, zinc gluconate, linoleol, benzyl alcohol, copper gluconate, coniarandrum sativum (contender) fruit oil, moringa pterygosperma seed extract, passiflora edulis seed oil, disodium stearyl glutamate, methicone, prunus armeniaca (apricot) kernel oil, aluminum starch octenylsuccinate, alumina, aluminum hydroxide, may contain: red 28 lake, red 7, iron oxides, bismuth oxychloride, titanium dioxide

G8622013 -FIL: B163208/3



e 30 ml 1.01 FL OZ.

## ARMANI PRIMA

color control  
glow moisturizer

Sunscreen  
Broad Spectrum  
SPF35

1

GIORGIO ARMANI

e 30 ml 1.01 FL OZ.

COLOR CONTROL GLOW MOISTURIZER  
Broad Spectrum SPF 35

ARMANI PRIMA, advanced skincare for day-long make-up glow.

This tinted skincare and make-up hybrid formula hydrates and refreshes the skin, for an immediate anti-fatigue effect. An incredibly lightweight texture that covers imperfections, redness and evens out complexion. For skin that radiates with a natural-looking glow all day long. The appearance of fine lines and pores are reduced. Endorsed by our face designers. Tested under dermatological control for safety.

THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS  
GIORGIO ARMANI PARFUMS,  
16, PLACE VENDÔME, 75001 PARIS.  
LUXURY PRODUCTS LLC,  
10 HUDSON YARDS, NEW YORK, N.Y. 10001  
IMP. BY DESIGNER FRAGRANCES,  
MONTREAL, CANADA, H4T 1K5.  
[TSA.75000.93584.ST.QUEEN.CEDEX.FR](http://TSA.75000.93584.ST.QUEEN.CEDEX.FR)  
MADE IN FRANCE

QUESTIONS OR  
COMMENTS? CONTACT:  
GIORGIO ARMANI  
PARFUMS,  
LUXURY PRODUCTS LLC,  
10 HUDSON YARDS, NEW  
YORK, NY 10001  
FOR MORE INFORMATION  
ON THIS:  
[ARMANIBEAUTY.COM](http://ARMANIBEAUTY.COM)

## GIORGIO ARMANI ARMANIPRIMA COLOR CONTROL GLOW MOISTURIZER BROAD SPECTRUM SPF 35 SUNSCREEN

octinoxate and titanium dioxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-037
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
-----------------	-------------------	----------

<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	19 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>BETAINE</b> (UNII: 3SCV180C9W)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>DIISOSTEARYL MALATE</b> (UNII: QBS8A3XZGQ)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>MACADAMIA OIL</b> (UNII: 515610SU8C)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ADENOSINE</b> (UNII: K72T3FS567)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>MAGNESIUM ASPARTATE</b> (UNII: R17X820ROL)	
<b>ETHYLHEXYL HYDROXYSTEARATE</b> (UNII: B7180BVV5E)	
<b>ETHYL MENTHANE CARBOXAMIDE</b> (UNII: 6S7S02945H)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DIMETHICONOL (100000 CST)</b> (UNII: OSA9UP217S)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE)</b> (UNII: H895X08VNQ)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>ZINC GLUCONATE</b> (UNII: U6WSN5SQ1Z)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>COPPER GLUCONATE</b> (UNII: RV823G6G67)	
<b>CORIANDER OIL</b> (UNII: 7626GC95E5)	
<b>MORINGA OLEIFERA SEED</b> (UNII: TIX5482832)	
<b>PASSIFLORA EDULIS SEED OIL</b> (UNII: F3VOA31UHQ)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>METHICONE (20 CST)</b> (UNII: 6777U11MKT)	
<b>APRICOT KERNEL OIL</b> (UNII: 54JB35T06A)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>D&amp;C RED NO. 7</b> (UNII: ECW0LZ41X8)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-037-01	1 in 1 CARTON	01/15/2018	
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	01/15/2018	

**Labeler** - L'Oreal USA Products Inc (002136794)**Establishment**

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-037) , pack(49967-037)

**Establishment**

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-037)

Revised: 2/2018

-L'Oreal USA Products Inc