

**GIORGIO ARMANI MAESTRO UV SKIN DEFENSE PRIMER BROAD SPECTRUM SPF 50  
SUNSCREEN- avobenzone, octinoxate and octisalate 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.*

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**Drug Facts**

**Active ingredients**

Avobenzone 3%

Octinoxate 7.49%

Octisalate 5%

**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**

**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:

- shake well before 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

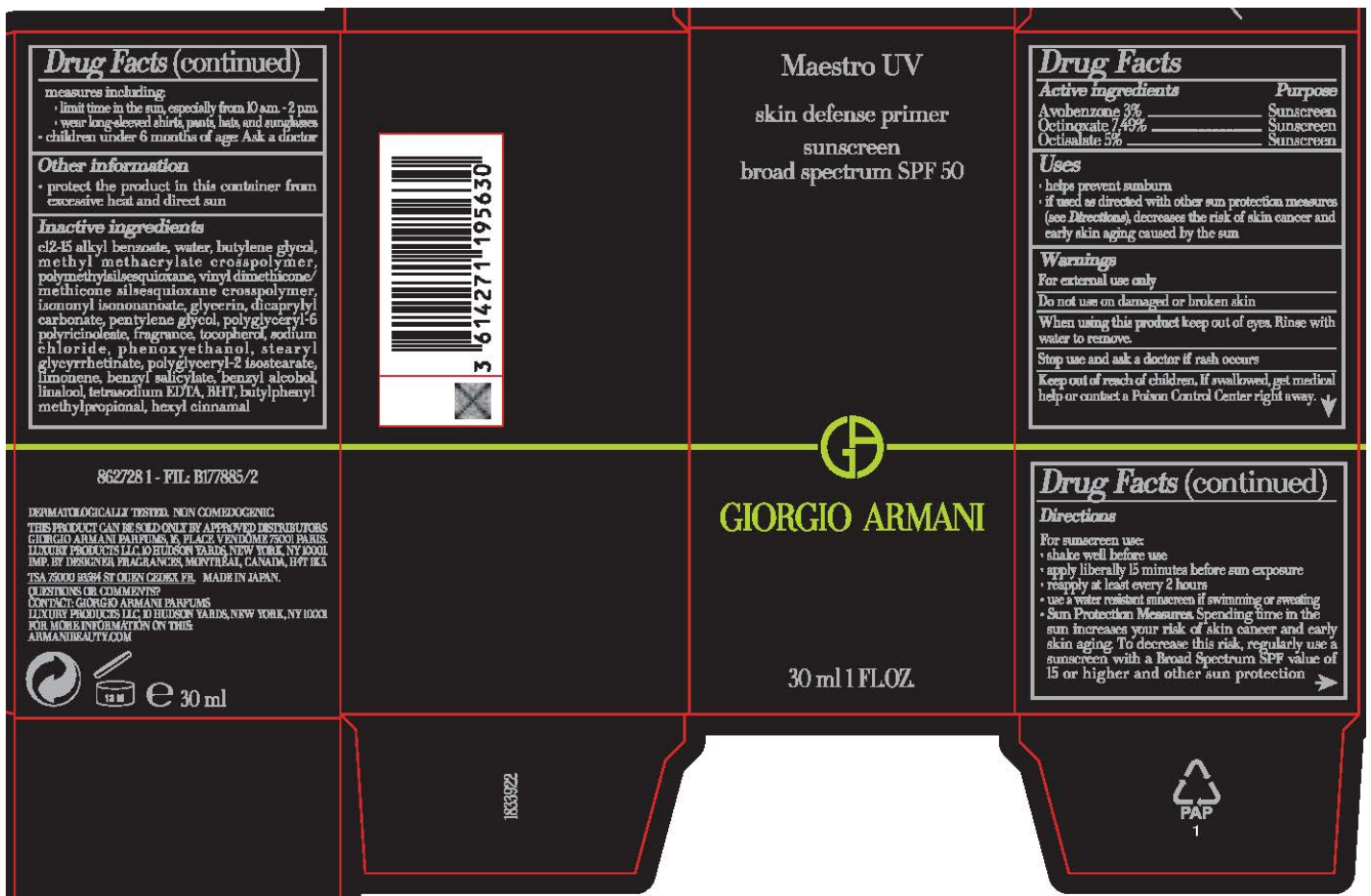
### **Inactive ingredients**

c12-15 alkyl benzoate, water, butylene glycol, methyl methacrylate crosspolymer, polymethylsilsesquioxane, vinyl dimethicone/methicone silsesquioxane crosspolymer, isononyl isononanoate, glycerin, dicaprylyl carbonate, pentylene glycol, polyglyceryl-6 polyricinoleate, fragrance, tocopherol, sodium chloride, phenoxyethanol, stearyl glycyrrhetinate, polyglyceryl-2 isostearate, limonene, benzyl salicylate, benzyl alcohol, linalool, tetrasodium EDTA, BHT, butylphenyl methylpropional, hexyl cinnamal

### **Questions or comments?**

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## GIORGIO ARMANI MAESTRO UV SKIN DEFENSE PRIMER BROAD SPECTRUM SPF 50 SUNSCREEN

avobenzone, octinoxate and octisalate lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-563
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	74.9 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0K00R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
POLYMETHYLSILSESQUOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
VINYL DIMETHICONE/METHICONE SILSESQUOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	

ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)
GLYCERIN (UNII: PDC6A3C0OX)
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
TOCOPHEROL (UNII: R0ZB2556P8)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
STEARYL GLYCYRRHETINATE (UNII: 3YYE6VJS0P)
POLYGLYCERYL-2 MONOISOSTEARATE (UNII: 7B8OE71MQC)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
BENZYL SALICYLATE (UNII: WAO5MKN9TU)
BENZYL ALCOHOL (UNII: LKG8494WBH)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
EDETATE SODIUM (UNII: MP1J8420LU)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-563-01	1 in 1 CARTON	06/01/2016	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-563-02	1 in 1 CARTON	06/01/2016	
2		5 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	06/01/2016	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Nippon Shikizai, Inc.		694869178	manufacture(49967-563)

### Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-563)