

GIORGIO ARMANI MAESTRO GLOW NOURISHING FUSION MAKEUP BROAD SPECTRUM SPF 30 SUNSCREEN- octinoxate liquid

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 ingredient

Octinoxate 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

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:

- shake well before use

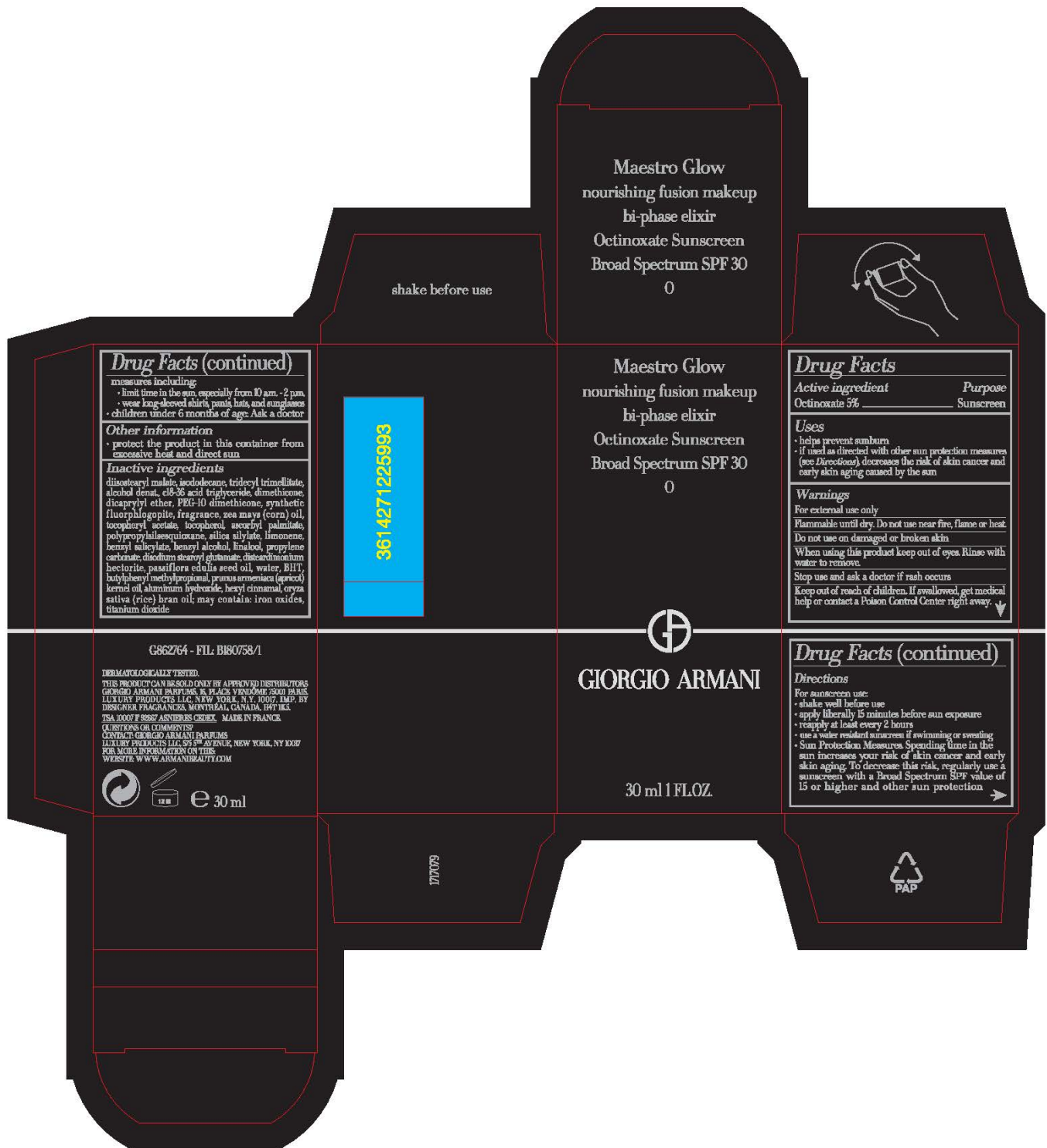
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen 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

diisostearyl malate, isododecane, tridecyl trimellitate, alcohol denat., C18-36 acid triglyceride, dimethicone, dicaprylyl ether, PEG-10 dimethicone, synthetic fluorphlogopite, fragrance, zeo mays (corn) oil, tocopheryl acetate, tocopherol, ascorbyl palmitate, polypropylsilsesquioxane, silica silylate, limonene, benzyl salicylate, benzyl alcohol, linalool, propylene carbonate, disodium stearyl glutamate, disteardimonium hectorite, passiflora edulis seed oil, water, BHT, butylphenyl methylpropional, prunus armeniaca (apricot) kernel oil, aluminum hydroxide, hexyl cinnamal, oryza sativa (rice) bran oil; may contain: iron oxides, titanium dioxide



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octinoxate liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-599
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ISODODECANE (UNII: A8289P68Y2)	
TRIDECYL TRIMELLITATE (UNII: FY36J270ES)	
ALCOHOL (UNII: 3K9958V90M)	
C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CORN OIL (UNII: 8470G57WFM)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)	
WATER (UNII: 059QF0K00R)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-599-01	1 in 1 CARTON	07/01/2015	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-599-02	1 in 1 CARTON	07/01/2015	
2		15 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 not final	part352	07/01/2015	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-599)

Revised: 7/2017

L'Oreal USA Products Inc