

GIORGIO ARMANI MAESTRO FUSION MAKEUP BROAD SPECTRUM SPF 15

SUNSCREEN- octinoxate 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 ingredient

Octinoxate 3%

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

cyclohexasiloxane, dimethicone, isododecane, alcohol denat., vinyl dimethicone/methicone silsesquioxane crosspolymer, phenyl trimethicone, acrylates/polytrimethylsiloxymethacrylate copolymer, PEG-10 dimethicone, disteardimonium hectorite, fragrance, nelumbium speciosum flower extract, limonene, benzyl salicylate, synthetic fluorophlogopite, linalool, benzyl alcohol, propylene carbonate, caprylic/capric triglyceride, disodium stearyl glutamate, water, citrus aurantium amara (bitter orange) flower oil, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal; may contain: iron oxides, titanium dioxide

<p>Drug Facts (continued)</p> <ul style="list-style-type: none">• 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:<ul style="list-style-type: none">• 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 <p>Other information</p> <ul style="list-style-type: none">• protect the product in this container from excessive heat and direct sun <p>Inactive ingredients</p> <p>cyclohexasiloxane, dimethicone, isododecane, alcohol denat., vinyl dimethicone/methicone silsesquioxane crosspolymer, phenyl trimethicone, acrylates/polytrimethylsiloxymethacrylate copolymer, PEG-10 dimethicone, disteardimonium hectorite, fragrance, nelumbium speciosum flower extract, limonene, benzyl salicylate, synthetic fluorophlogopite, linalool, benzyl alcohol, propylene carbonate, caprylic/capric triglyceride, disodium stearyl glutamate, water, citrus aurantium amara (bitter orange) flower oil, butylphenyl methylpropional, aluminum hydroxide, hexyl cinnamal; may contain: iron oxides, titanium dioxide</p> <p>G861358 - FIL: B48256/7</p>	<p>Maestro</p> <p>OCTINOXATE SUNSCREEN</p> <p>fusion makeup</p> <p>BROAD SPECTRUM SPF 15</p> <p>2</p> <p></p> <p>GIORGIO ARMANI</p> <p>30 ml / 1 FL.OZ.</p>	<p>Drug Facts</p> <table border="1"><thead><tr><th>Active ingredient</th><th>Purpose</th></tr></thead><tbody><tr><td>Octinoxate 3%</td><td>Sunscreen</td></tr></tbody></table> <p>Uses</p> <ul style="list-style-type: none">• 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 <p>Warnings</p> <p>For external use only</p> <p>Flammable until dry. Do not use near fire, flame or heat.</p> <p>Do not use on damaged or broken skin.</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>For sunscreen use:</p> <ul style="list-style-type: none">• shake well before use• apply liberally 15 minutes before sun exposure• reapply at least every 2 hours	Active ingredient	Purpose	Octinoxate 3%	Sunscreen
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GIORGIO ARMANI MAESTRO FUSION MAKEUP BROAD SPECTRUM SPF 15 SUNSCREEN

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-714
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISODODECANE (UNII: A8289P68Y2)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
WATER (UNII: 059QF0KO0R)	
CITRUS AURANTIUM FLOWER OIL (UNII: D4BGE910XH)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
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:49967-714-01	1 in 1 CARTON	06/01/2012	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		
2	NDC:49967-714-02	1 in 1 CARTON	06/01/2012	11/30/2017
2		3 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49967-714-03	1 mL in 1 PACKET; Type 0: Not a Combination Product	06/01/2012	11/30/2017
4	NDC:49967-714-04	15 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2012	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-714)

Revised: 11/2017 L'Oreal USA Products Inc