GIORGIO ARMANI MAESTRO SUMMER BROAD SPECTRUM SPF 15 SUNSCREENoctinoxate 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 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

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

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



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octinoxate liquid

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-930	
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		
DIMETHICO NE (UNII: 92RU3N3Y1O)			
CYCLOMETHICONE 6 (UNII: XHK3U310BA)			
ISODODECANE (UNII: A8289P68Y2)			

ALCOHOL (UNII: 3K9958V90M)	
VINYL DIMETHICONE/METHICONE SILSESQUIO XANE CROSSPOLYMER (UNII: 9 NH1UDD2RR)	
PHENYL TRIMETHICO NE (UNII: DR0 K5NOJ4R)	
PEG-10 DIMETHICO NE (600 CST) (UNII: 8 PR7V1SVM0)	
DISTEARDIMO NIUM HECTO RITE (UNII: X687XDK09L)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
LIMO NENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
LINALOOL, (+/-)- (UNII: D81QY6188E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DISODIUM STEARO YL GLUTAMATE (UNII: 45ASM2L11M)	
WATER (UNII: 059QF0KO0R)	
CITRUS AURANTIUM FLO WER OIL (UNII: D4BGE910XH)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540 GJV69)	
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)	
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-930-01	1 in 1 CARTON	0 1/0 1/20 15	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-930-02	1 in 1 CARTON	0 1/0 1/20 15	11/30/2017
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	0 1/0 1/20 15		

Labeler - L'Oreal USA Products Inc (002136794)

Establishment					
Name	Address	ID/FEI	Business Operations		
SICOS ET CIE		276993581	manufacture(49967-930)		

Revised: 11/2017 L'Oreal USA Products Inc