GIORGIO ARMANI LASTING SILK UV FOUNDATION BROAD SPECTRUM SPF 20 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 3%

Titanium dioxide 6.2%

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

water, cyclopentasiloxane, alcohol denat., butylene glycol, phenyl trimethicone, PEG-10 dimethicone, squalane, fragrance, magnesium sulfate, talc, nylon-12, maltitol, limonene, benzyl salicylate, linalool, benzyl alcohol, sorbitol, bis-PEG/PPG-14/14 dimethicone, disodium stearoyl glutamate, butylphenyl ethylpropional, aluminum hydroxide, hexyl cinnamal; may contain: iron oxides, titanium dioxide

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octinoxate and titanium dioxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49967-243
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	62 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
SQUALANE (UNII: GW89575KF9)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
TALC (UNII: 7SEV7J4R1U)	
NYLON-12 (UNII: 446U8J075B)	
MALTITOL (UNII: D65DG142WK)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SORBITOL (UNII: 506T60A25R)	
BIS-PEG/PPG-14/14 DIMETHICONE (UNII: X2I70H0QJE)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49967-243-01	1 in 1 CARTON	03/01/2009	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-243-02	1 in 1 CARTON	03/01/2009	11/30/2017
2		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49967-243-03	1 mL in 1 PACKET; Type 0: Not a Combination Product	03/01/2009	11/30/2017

4	NDC:49967-243-04	1 in 1 CARTON	03/01/2009	
4		18 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	03/01/2009	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Sicos et Cie		276993581	manufacture(49967-243)

Revised: 11/2017 L'Oreal USA Products Inc