

**YVES SAINT LAURENT ALL HOURS PRIMER BROAD SPECTRUM SPF 18 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 6.5%

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.

Avoid fire, flame and heat during application.

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, dimethicone, isododecane, alcohol, trimethylsiloxysilicate, butylene glycol, PEG-10 dimethicone, titanium dioxide, perlite, nylon-12, lauryl methacrylate/glycol dimethacrylate crosspolymer, HDI/trimethylol hexyllactone crosspolymer, bismuth oxychloride, BIS-PEG/PPG-14/14 dimethicone, magnesium sulfate, silica silylate, phenoxyethanol, disteardimonium hectorite, aluminum hydroxide, dipentaerythrityl tetrahydroxystearate/tetraisoostearate, hydrogen dimethicone, tocopherol, propylene glycol, silica, iron oxides, BHT, synthetic fluorophlogopite, rosa centifolia flower extract, disodium stearyl glutamate

<p>Drug Facts (continued)</p> <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>water, dimethicone, isododecane, alcohol, trimethylsiloxysilicate, butylene glycol, PEG-10 dimethicone, titanium dioxide, perlite, nylon-12, lauryl methacrylate/glycol dimethacrylate crosspolymer, HDI/trimethylol hexyllactone crosspolymer, bismuth oxychloride, BIS-PEG/PPG-14/14 dimethicone, magnesium sulfate, silica silylate, phenoxyethanol, disteardimonium hectorite, aluminum hydroxide, dipentaerythrityl tetrahydroxystearate/tetraisoostearate, hydrogen dimethicone, tocopherol, propylene glycol, silica, iron oxides, BHT, synthetic fluorophlogopite, rosa centifolia flower extract, disodium stearyl glutamate</p>	<p>An instant perfecting layer for a lasting flawless complexion. Long-wear: This advanced primer is enriched with a lasting complex to improve foundation's wear and hold, for a « just applied » make-up result all day long. Velvet shine-free complexion: A combination of ingredients keep the skin looking matte, yet non-dry throughout the day. Pore minimizing effect: With an ultra-fresh lightweight texture, this primer helps immediately smooth the skin's surface and reduce the appearance of pores. Suitable for all skin types, including sensitive skin. Dermatologically tested. Non-comedogenic.</p>	<p>ALL HOURS PRIMER</p> <p>OCTINOXATE SUNSCREEN BROAD SPECTRUM SPF 18</p> <p>FLAWLESS MATTE LONG-WEAR PRIMER</p> 	<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Octinoxate 6.5%</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. Avoid fire, flame and heat during application.</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 generously 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: <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 	Active ingredient	Purpose	Octinoxate 6.5%	Sunscreen
Active ingredient	Purpose						
Octinoxate 6.5%	Sunscreen						
<p>8096145 - F.I.L. B197352/1</p> <p>QUESTIONS OR COMMENTS? CONTACT: YVES SAINT LAURENT, 10 HUDSON YARDS, NEW YORK, NY 10001 FOR MORE INFORMATION ON THIS: WEBSITE: www.yvesbeauty.com</p> <p>THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS</p> <p>© YVES SAINT LAURENT YSL BEAUTE</p> <p>281, RUE SAINT HONORE, 75008 PARIS LUXURY PRODUCTS LLC, NEW YORK, NY 10001 Imp. By YSL BEAUTE CANADA, MONTREAL, H4T 1H6 TSA 75000 93624 ST. QUEN, QUEBEC FR MADE IN FRANCE yvesbeauty.com</p>  <p>CAUTION: FLAMMABLE UNTIL DRY. KEEP AWAY FROM FLAME AND HEAT</p>	 <p>3 614271 740304</p> 	 <p>1.35 fl. oz. e 40 ml</p>					

YVES SAINT LAURENT ALL HOURS PRIMER BROAD SPECTRUM SPF 18 SUNSCREEN
 octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-403
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	65 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ISODODECANE (UNII: A8289P68Y2)	
ALCOHOL (UNII: 3K9958V90M)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PERLITE (UNII: 0SG101ZGK9)	
NYLON-12 (UNII: 446U8J075B)	
LAURYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EX0F4CZ66H)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
BIS-PEG/PPG-14/14 DIMETHICONE (UNII: X2I70H0QJE)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TETRAISO STEARATE (UNII: 230K0823CE)	
HYDROGEN DIMETHICONE (13 CST) (UNII: 4QGR4P2Y0I)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-403-01	1 in 1 CARTON	06/01/2017	
1		40 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-403-02	1 mL in 1 PACKET; Type 0: Not a Combination Product	06/01/2017	11/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	06/01/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-403)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-403)

Revised: 12/2017

L'Oreal USA Products Inc