

YVES SAINT LAURENT LE TEINT ENCRE DE PEAU FUSION INK FOUNDATION 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 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

Caution:

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 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:
 - 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, disteardimonium hectorite, PEG-10 dimethicone, synthetic fluorphlogopite, water, propylene carbonate, disodium stearyl glutamate, silica silylate, fragrance, calophyllum inophyllum seed oil, aluminum hydroxide, benzyl alcohol; may contain: titanium dioxide, iron oxides

<p>Drug Facts (continued)</p> <p>Inactive ingredients dimethicone, cyclohexasiloxane, isododecane, alcohol denat., vinyl dimethicone/methicone silsesquioxane crosspolymer, phenyl trimethicone, disteardimonium hectorite, PEG-10 dimethicone, synthetic fluorphlogopite, water, propylene carbonate, disodium stearyl glutamate, silica silylate, fragrance, calophyllum inophyllum seed oil, aluminum hydroxide, benzyl alcohol; may contain: titanium dioxide, iron oxides</p> <p> CAUTION: FLAMMABLE UNTIL DRY. KEEP AWAY FROM FLAME AND HEAT.</p> <p>THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS © YVES SAINT LAURENT YSL BEAUTE 231, RUE SAINT HONORE, 75008 PARIS LUXURY PRODUCTS L.L.O., NEW YORK, NY 10017 Imp. By YSL BEAUTE CANADA, MONTREAL, H4T 1K5 TSA 10007 F 92867 ASNIERES CEDEX MADE IN FRANCE</p> <p> 12 M</p>	<p>The first YSL ink foundation: feels like a feather, wears like an ink - perfect color all day. The hybrid light-smooth texture melts into the skin for seamlessly even, soft-matte coverage. Hybrid-stain technology ensures makeup stays comfortable and flawless all day. The custom applicator applies the ideal amount of foundation to the hand or to the face. Total fusion with the skin for the freedom of uncompromising color.</p> <p>QUESTIONS OR COMMENTS? CONTACT: YVES SAINT LAURENT 575 5TH AVE. NEW YORK, NY 10017</p> <p>FOR MORE INFORMATION ON THIS: WEBSITE: www.yslbeautyus.com Imp. By YSL BEAUTE CANADA MONTREAL H4T 1K5 CANADA</p> <p> 3 365 440 677890</p>	<p>LE TEINT ENGRE DE PEAU FUSION INK FOUNDATION</p> <p>OCTINOXATE SUNSCREEN BROAD SPECTRUM SPF 18</p> <p>ALL DAY PERFECTION FEATHERLIGHT TEXTURE</p> <p></p> <p>B 10 PORCELAIN</p> <p>YVES SAINT LAURENT 0.84 fl.oz. e 25 ml</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>Caution: 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. – 2p.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>G862396 - F.I.L. B165892/3</p>	Active ingredient	Purpose	Octinoxate 3%	Sunscreen
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Octinoxate 3%	Sunscreen						

YVES SAINT LAURENT LE TEINT ENCRE DE PEAU FUSION INK FOUNDATION BROAD SPECTRUM SPF 18 SUNSCREEN

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-789
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
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ISODODECANE (UNII: A8289P68Y2)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
WATER (UNII: 059QF0K00R)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
TAMANU OIL (UNII: JT3LVK84A1)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-789-01	1 in 1 CARTON	08/01/2014	
1		25 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-789-02	1 in 1 CARTON	08/01/2014	
2		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:49967-789-03	0.27 mL in 1 PACKAGE; Type 0: Not a Combination Product	08/01/2014	11/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/01/2014	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Sicos et Cie		276993581	manufacture(49967-789)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-789)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-789)

Revised: 12/2017

L'Oreal USA Products Inc