

**YVES SAINT LAURENT ALL HOURS FOUNDATION BROAD SPECTRUM SPF 20
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

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, cyclopentasiloxane, alcohol denat., isododecane, acrylates/polytrimethylsiloxymethacrylate copolymer, butylene glycol, glycerin, polymethylsilsesquioxane, cetyl PEG/PPG-10/1 dimethicone, synthetic fluorophlogopite, isohexadecane, polyglyceryl-4 isostearate, magnesium sulfate, disodium stearyl glutamate, fragrance, perlite, saccharomyces/xylinum/black tea ferment, silica silylate, aluminum hydroxide, butyrospermum parkii (shea) seedcake extract, hydroxyethylcellulose, BHT, phenoxyethanol, sodium citrate, benzyl alcohol, linalool, citric acid, potassium sorbate, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, biotin; may contain: titanium dioxide, iron oxides

Drug Facts (continued)

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G982 121 - F.I.L. B202874/1



CAUTION : FLAMMABLE UNTIL DRY. KEEP AWAY FROM FLAME AND HEAT.

QUESTIONS OR COMMENTS? CONTACT:
YVES SAINT LAURENT 10 HUDSON YARDS,
901 W 30TH ST, NEW YORK, NY 10001
FOR MORE INFORMATION ON THIS:
WEBSITE: www.yslbeautyus.com

SAMPLE - NOT FOR SALE
THIS PRODUCT CAN BE SOLD ONLY
BY APPROVED DISTRIBUTORS
© YVES SAINT LAURENT
YSL BEAUTE, 281, RUE SAINT HONORE, 75008 PARIS
LUXURY PRODUCTS LLC, NEW YORK, NY 10001
Imp. By/par YSL BEAUTE CANADA, MONTREAL, H4T 1H5
TSA 75000033884 ST. OUBIN CEDEX FR
MADE IN FRANCE
yslbeauty.com



Seal Vector

ALL HOURS FOUNDATION

OCTINOXATE SUNSCREEN
BROAD SPECTRUM SPF 20

UP TO 24 H WEAR
FLAWLESS MATTE
FULL COVERAGE
OIL-FREE



B 45
BISQUE

YVES SAINT LAURENT

0.33 fl.oz. e 10 ml

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Drug Facts (continued)

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G992 121 - F.I.L. B202974/1



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octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-362
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
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ALCOHOL (UNII: 3K9958V90M)	

ISODODECANE (UNII: A8289P68Y2)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
GLYCERIN (UNII: PDC6A3C0OX)
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
ISOHEXADECANE (UNII: 918X10UF1E)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)
PERLITE (UNII: 0SG101ZGK9)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
HYDROXYETHYL CELLULOSE (100 MPAS AT 2%) (UNII: R33S7TK2EP)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
BENZYL ALCOHOL (UNII: LKG8494WBH)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
BIOTIN (UNII: 6SO6U10H04)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-362-01	1 in 1 CARTON	06/01/2017	
1		25 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-362-02	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/01/2017	
3	NDC:49967-362-03	1 in 1 CARTON	06/01/2017	
3		10 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:49967-362-04	1 in 1 CARTON	06/01/2017	
4		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:49967-362-05	1 mL in 1 PACKET; Type 0: Not a Combination Product	06/01/2017	
6	NDC:49967-362-06	1.2 mL in 1 BLISTER PACK; Type 0: Not a Combination Product	02/08/2019	

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(49967-362) , pack(49967-362)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-362)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-362)

Revised: 2/2019

L'Oreal USA Products Inc