

**YVES SAINT LAURENT FOREVER LIGHT CREATOR CC PRIMER COLOR
CORRECTING PRIMER BROAD SPECTRUM SPF 35 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 5%

Titanium dioxide 6.3%

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

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

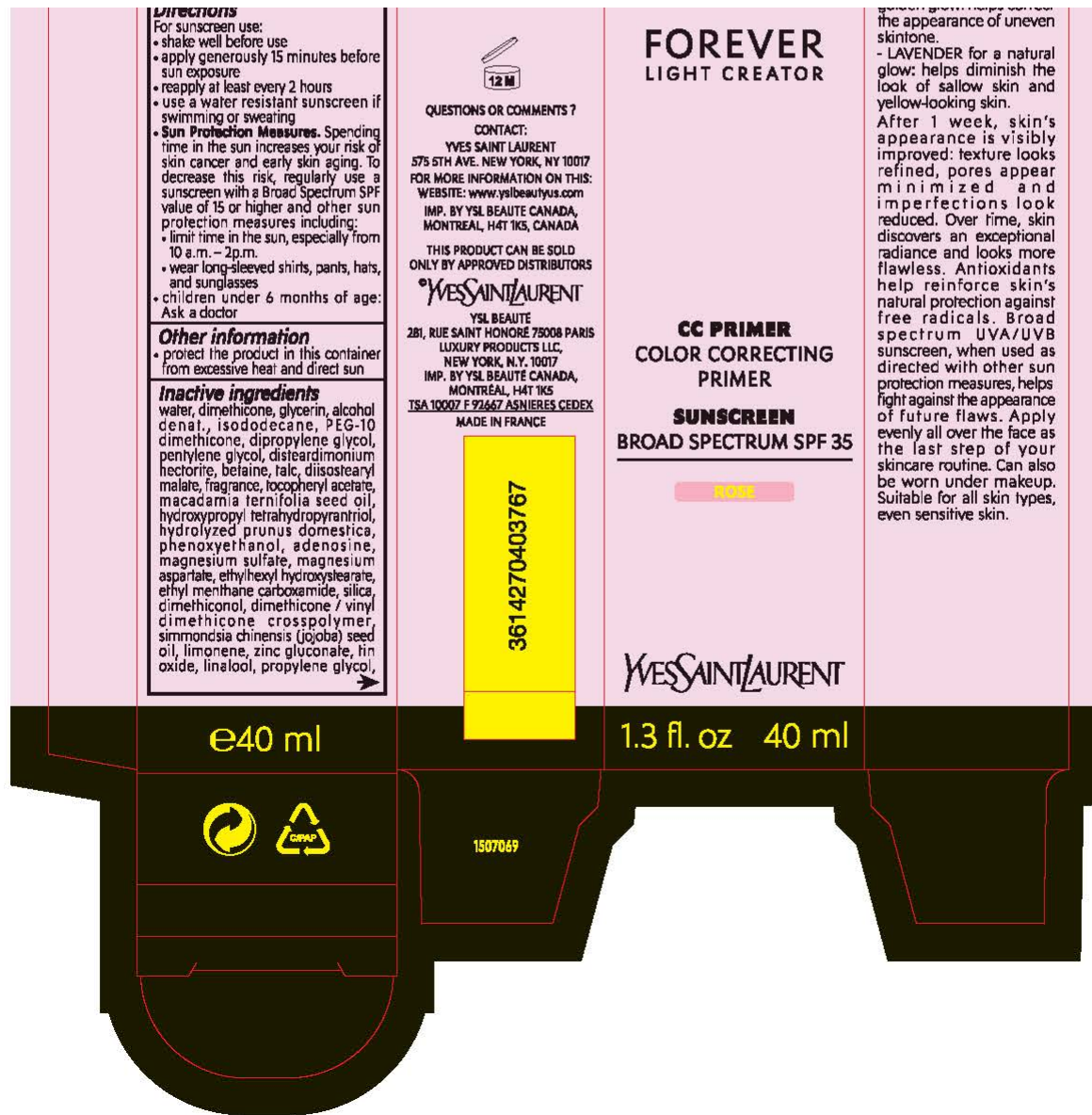
Other information

protect the product in this container from excessive heat and direct sun

Inactive ingredients

water, dimethicone, glycerin, alcohol denat., isododecane, PEG-10 dimethicone, dipropylene glycol, pentylene glycol, disteardimonium hectorite, betaine, talc, diisostearyl malate, fragrance, tocopheryl acetate, macadamia ternifolia seed oil, hydroxypropyl tetrahydropyrantriol, hydrolyzed prunus domestica, phenoxyethanol, adenosine, magnesium sulfate, magnesium aspartate, ethylhexyl hydroxystearate, ethyl menthane carboxamide, silica, dimethiconol, dimethicone/vinyl dimethicone crosspolymer, simmondsia chinensis (jojoba) seed oil, limonene, zinc gluconate, tin oxide, linalool, propylene glycol, copper gluconate, coriandrum sativum (coriander) fruit oil, moringa pterygosperma seed extract, carrageenan, passiflora edulis seed oil, disodium stearyl glutamate, disodium phosphate, butylene glycol, BHT, citric acid, methicone, prunus armeniaca (apricot) kernel oil, aluminum starch octenylsuccinate, alumina, aluminum hydroxide; may contain: mica, red 28 lake, red 7, iron oxides, carmine, ferric ammonium ferrocyanide, bismuth oxychloride, titanium dioxide





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octinoxate and titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-376
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	63 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
ISODODECANE (UNII: A8289P68Y2)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
BETAINE (UNII: 3SCV180C9W)	
TALC (UNII: 7SEV7J4R1U)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
MACADAMIA OIL (UNII: 515610SU8C)	
HYDROXYPROPYL TETRAHYDROPYRANTRIOL (UNII: 4U3GMG1OT1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ADENOSINE (UNII: K72T3FS567)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
ETHYLHEXYL HYDROXYSTEARATE (UNII: B7180BVV5E)	
ETHYL MENTHANE CARBOXAMIDE (UNII: 6S7S02945H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNQ)	
JOJOBA OIL (UNII: 724GKU717M)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
STANNIC OXIDE (UNII: KM7N50LOS6)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
COPPER GLUCONATE (UNII: RV823G6G67)	
CORIANDER OIL (UNII: 7626GC95E5)	
MORINGA OLEIFERA SEED (UNII: TIX5482832)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
PASSIFLORA EDULIS SEED OIL (UNII: F3VOA31UHQ)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
APRICOT KERNEL OIL (UNII: 54JB35T06A)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
MICA (UNII: V8A1AW0880)	
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC AMMONIUM FERROCYANIDE (UNII: 9R0NVI936I)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-376-01	1 in 1 CARTON	02/01/2016	
1		40 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-376-02	1 mL in 1 PACKET; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/01/2016	

Labeler - L'Oreal USA Products Inc. (002136794)**Establishment**

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-376) , pack(49967-376)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-376)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(49967-376)

Revised: 12/2017

L'Oreal USA Products Inc.