

**LANCÔME PARIS RENERGIE LIFT MAKEUP BROAD SPECTRUM SPF 27 SUNSCREEN-
octinoxate and titanium dioxide liquid**

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 7.5%

Titanium dioxide 3.2%

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

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:

- 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

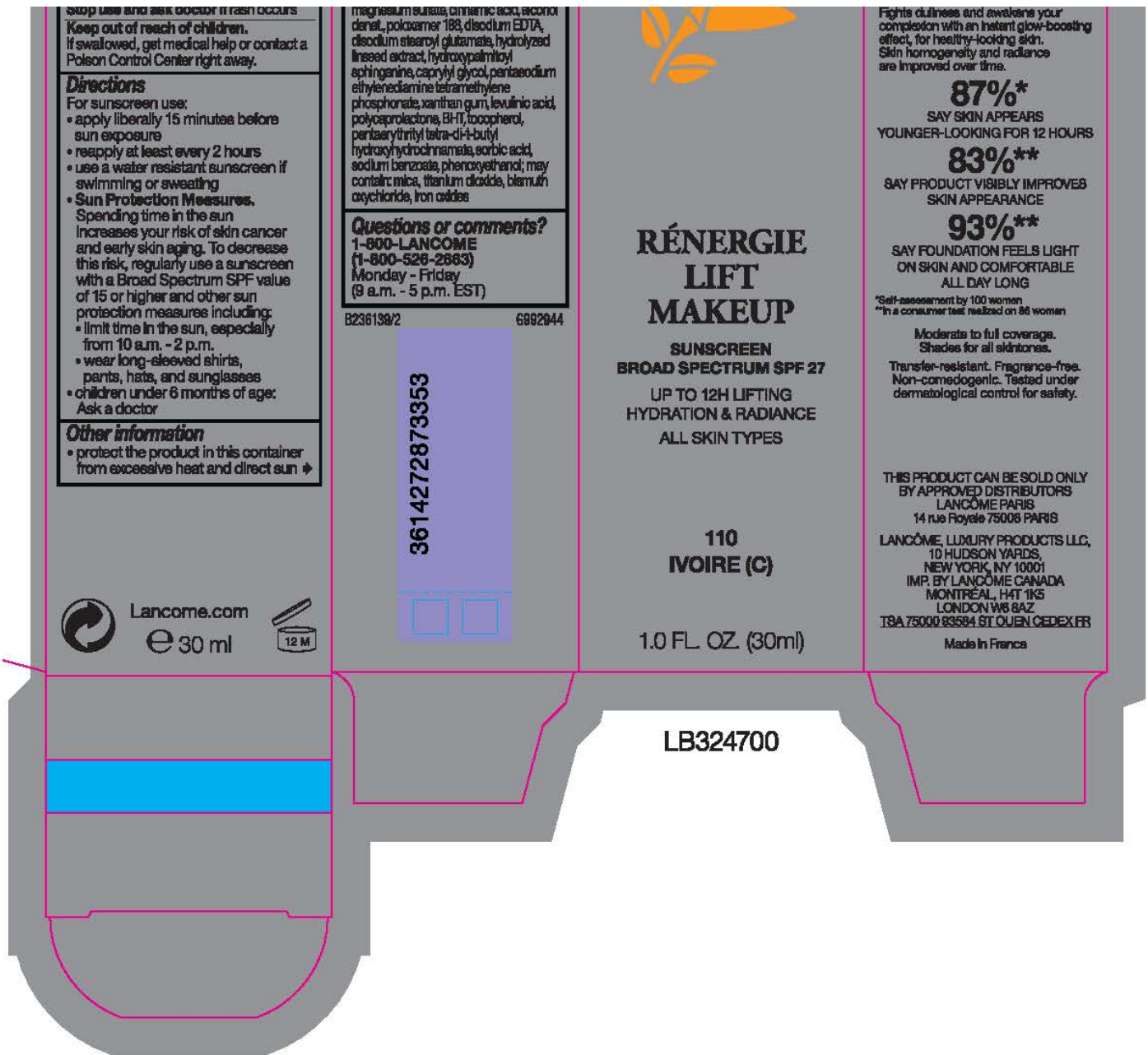
water, cyclopentasiloxane, phenyl trimethicone, cyclohexasiloxane, butylene glycol, propanediol, cetyl PEG/PPG-10/1 dimethicone, pentylene glycol, polyglyceryl-4 isostearate, zea mays (corn) kernel extract, glycine soja (soybean) oil, copernicia cerifera (carnauba) wax, iris florentina root extract, cyathaea medullaris leaf extract; PEG-10 dimethicone, PEG-30 glyceryl stearate, PEG/PPG-18/18 dimethicone, ceramide NP, sorbitol, glycerin, glyceryl caprylate, dimethicone, caffeine, lecithin, sodium levulinate, silylate, cellulose gum, 2-oleamido-1,3-octadecanediol, perlite, aluminum hydroxide, guanosine, magnesium sulfate, cinnamic acid, alcohol denat., poloxamer 188, disodium EDTA, disodium stearyl glutamate, hydrolyzed linseed extract, hydroxypalmitoyl sphinganine, caprylyl glycol, pentasodium ethylenediamine tetramethylene phosphonate, xanthan gum, levulinic acid, polycaprolactone, BHT, tocopherol, pentaerytrityl tetra-di-t-butyl hydroxyhydrocinnamate, sorbic acid, sodium benzoate, phenoxyethanol; may contain: titanium dioxide, bismuth oxychloride, iron oxides

Questions or comments?

1-800-LANCOME (1-800-526-2663)

Monday - Friday (9 a.m. - 5 p.m. EST)





LANCÔME PARIS RÉNERGIE LIFT MAKEUP BROAD SPECTRUM SPF 27 SUNSCREEN

octinoxate and titanium dioxide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-335
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	32 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PROPANEDIOL (UNII: 5965N8W85T)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 1.5) (UNII: V2W71V8T0X)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
CORN (UNII: 0N8672707O)	
SOYBEAN OIL (UNII: 241ATL177A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
IRIS X GERMANICA NOSTHOVAR. FLORENTINA ROOT (UNII: M30XO5X4XD)	
CYATHEA MEDULLARIS LEAF (UNII: G65ROR2RKA)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
PEG-30 GLYCERYL STEARATE (UNII: MW8WP96K3D)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
CERAMIDE NP (UNII: 4370DF050B)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAFFEINE (UNII: 3G6A5W338E)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
9-OCTADECENAMIDE, N-(2-HYDROXY-1-(HYDROXYMETHYL)HEPTADECYL)-, (9Z)- (UNII: 30D478BUNR)	
PERLITE (UNII: 0SG101ZGK9)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
GUANOSINE (UNII: 12133JR80S)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
CINNAMIC ACID (UNII: U14A832J8D)	
ALCOHOL (UNII: 3K9958V90M)	
POLOXAMER 188 (UNII: LQA7B6G8JG)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
HYDROXYPALMITOYL SPHINGANINE (UNII: NR33W2353T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
LEXIDRONAM PENTASODIUM (UNII: 2ZYX2V82AD)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LEVULINIC ACID (UNII: RYX5QG61EI)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)	
SORBIC ACID (UNII: X045WJ989B)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

MICA (UNII: V8A1AW0880)	
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-335-01	1 in 1 CARTON	10/30/2019	
1		30 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-335-02	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/30/2019	
3	NDC:49967-335-03	1 in 1 CARTON	10/30/2019	
3		10 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	10/30/2019	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-335) , pack(49967-335)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratoires Biocosm SARL		288479491	pack(49967-335)