

**LANCOME PARIS TEINT IDOLE ULTRA CUSHION BROAD SPECTRUM SPF 50  
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 5%

Titanium dioxide 10.59%

**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.**

Do not use near fire, flame or heat.

**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, isononyl isononanoate, alcohol denat., phenyl trimethicone, PEG-10 dimethicone, glycerin, bis-PEG/PPG-14/14 dimethicone, citrus aurantium dulcis (orange) fruit water, mentha piperita (peppermint) extract, RNA, zea mays (corn) kernel extract, rosa centifolia flower extract, sorbitol, saccharum officinarum (sugar cane) extract, vaccinium myrtillus fruit extract, talc, arginine, pyridoxine HCL, alumina, aluminum hydroxide, phenylalanine, magnesium sulfate, mannitol, ascorbyl glycoside, nylon-12, tyrosine, disodium adenosine triphosphate, disodium stearyl glutamate, propylene glycol, acer saccharum (sugar maple) extract, citrus limon (lemon) fruit extract, maltitol, gentiana lutea root extract, pentylene glycol, disteardimonium hectorite, histidine HCL, ethylhexyl hydroxystearate, BHT, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, sorbic acid, phenoxyethanol, fragrance, linalool, eugenol, alpha-isomethyl ionone, hexyl cinnamal, benzyl alcohol, benzyl salicylate; 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)

<p><b>Drug Facts (continued)</b></p> <p><b>Warnings:</b>  <b>For external use only.</b>        Flammable unitary. Do not use near fire, flame or heat.        Do not use on damaged or broken skin.  <b>When using this product, avoid hot or spicy foods when water is harmful.</b>        Stop use and ask a doctor if irritation occurs.        Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions:</b>  <b>For sunscreen use:</b>        • apply liberally 15 minutes before sun exposure        • reapply at least every 2 hours        • use a water resistant sunscreen if swimming or sweating  <b>Sun Protection Measures:</b> 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</p> <p><b>Other information</b>        • protect the product in this container from excessive heat and direct sun</p> <p>Lancome.com  <b>110 IVOIRE (C)</b>        13 g L9777 00</p>	<p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients</b>        water, cyclopentasiloxane, isononyl isononanoate, alcohol denat., phenyl trimethicone, PEG-10 dimethicone, glycerin, bis-PEG/PPG-14/14 dimethicone, citrus aurantium dulcis (orange) fruit water, mentha piperita (peppermint) extract, RNA, zea mays (corn) kernel extract, rosa centifolia flower extract, sorbitol, saccharum officinarum (sugar cane) extract, vaccinium myrtillus fruit extract, talc, arginine, pyridoxine HCL, alumina, aluminum hydroxide, phenylalanine, magnesium sulfate, mannitol, ascorbyl glycoside, nylon 12, tyrosine, disodium adenosine triphosphate, disodium stearyl glutamate, propylene glycol, acer saccharum (sugar maple) extract, citrus limon (lemon) fruit extract, maltitol, gentiana lutea root extract, pentylene glycol, disteardimonium hectorite, histidine HCL, ethylhexyl hydroxystearate, BHT, pentaerythrityl tetra-di-t-butyl hydroxyhydrocinnamate, sorbic acid, phenoxyethanol, fragrance, linalool, eugenol, alpha-isomethyl ionone, hexyl cinnamal, benzyl alcohol, benzyl salicylate; may contain: titanium dioxide, bismuth oxychloride, iron oxides</p> <p>3614271424235</p>	<p><b>LANCÔME</b>        PARIS</p> <p><b>TEINT IDOLE ULTRA CUSHION</b></p> <p>SUNSCREEN        BROAD SPECTRUM SPF 50        LIQUID CUSHION COMPACT        LONGWEAR - HIGH COVERAGE MAKEUP        OIL-FREE</p> <p>COVERAGE        ●●●●●</p> <p><b>110 IVOIRE (C)</b>        13 g 0.45 OZ.</p>	<p>Liquid Cushion Compact        Longwear - High Coverage Makeup        SPF 50</p> <p>Thanks to the new cushion technology, Lancôme introduces the 1st fragrance &amp; high coverage liquid cushion makeup compact. Complete coverage &amp; texture. Resistant all day long to make your complexion longer. Thanks to the Ultra Cushion effect, conceals blemishes and softens skin glow.</p> <p>Parfums Lancôme - Oil free        Non-comedogenic        Tested under dermatological control</p> <p><b>Questions or comments?</b>        1-800-LANCOME (1-800-526-2663)        Monday-Friday (9 a.m. - 5 p.m. EST)</p> <p>LANCÔME, L'ÉLÉPHANT PRODUCTIONS LLC, NEW YORK, NY 10017        110 IVOIRE (C) 110 IVOIRE (C)        13 g 0.45 OZ. L9777 00 (C)</p> <p>Medium Finish</p> <p><b>Drug Facts</b></p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Octinoxate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Titanium dioxide 11.5%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p><b>Use</b>        • helps prevent sunburn</p>	Active ingredients	Purpose	Octinoxate 5%	Sunscreen	Titanium dioxide 11.5%	Sunscreen
Active ingredients	Purpose								
Octinoxate 5%	Sunscreen								
Titanium dioxide 11.5%	Sunscreen								

# LANCÔME PARIS TEINT IDOLE ULTRA CUSHION BROAD SPECTRUM SPF 50 SUNSCREEN

octinoxate and titanium dioxide liquid

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-423
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 g
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	105.9 mg in 1 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>BIS-PEG/PPG-14/14 DIMETHICONE</b> (UNII: X2I70H0QJE)	
<b>ORANGE</b> (UNII: 5EVU04N5QU)	
<b>MENTHA PIPERITA</b> (UNII: 79M2M2UDA9)	
<b>SACCHAROMYCES CEREVISIAE RNA</b> (UNII: J17GBZ5VGX)	
<b>CORN</b> (UNII: 0N8672707O)	
<b>ROSA CENTIFOLIA FLOWER</b> (UNII: CS4TE8FF7O)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUGARCANE</b> (UNII: 81H2R5AOH3)	
<b>BILBERRY</b> (UNII: 9P2U39H18W)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ARGININE</b> (UNII: 94ZLA3W45F)	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV)	
<b>ALUMINUM OXIDE</b> (UNII: LM26O6933)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>PHENYLALANINE</b> (UNII: 47E5O17Y3R)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>ASCORBYL LACTOSIDE</b> (UNII: NJ3O2X7MF4)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>TYROSINE</b> (UNII: 42HK56048U)	
<b>ADENOSINE TRIPHOSPHATE DISODIUM</b> (UNII: 5L51B4DR1G)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ACER SACCHARUM BARK/SAP</b> (UNII: Z120VL0KAC)	
<b>LEMON</b> (UNII: 24RS0A988O)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>GENTIANA LUTEA ROOT</b> (UNII: S72O3284MS)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	

HISTIDINE MONOHYDROCHLORIDE (UNII: 1D5Q932XM6)
ETHYLHEXYL HYDROXYSTEARATE (UNII: B7I80BVV5E)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE) (UNII: 255PIF62MS)
SORBIC ACID (UNII: X045WJ989B)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
EUGENOL (UNII: 3T8H1794QW)
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)
BENZYL ALCOHOL (UNII: LKG8494WBH)
BENZYL SALICYLATE (UNII: WAO5MNK9TU)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)
FERRIC OXIDE RED (UNII: 1K09F3G675)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-423-01	1 in 1 CARTON	06/01/2016	
1		13 g in 1 CONTAINER; 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	06/01/2016	

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

Establishment			
Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-423)