

**LOREAL PARIS INFALLIBLE UP TO 24 H FRESH WEAR FOUNDATION BROAD SPECTRUM SPF 25 SUNSCREEN- octinoxate and titanium dioxide liquid**  
**L'Oreal USA Products Inc**

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**Drug Facts**

**Active ingredients**

Octinoxate 6.7%

Titanium dioxide 3.6%

**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:

- shake well
- 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, dimethicone, isododecane, alcohol denat., trimethylsiloxysilicate, butylene glycol, PEG-10 dimethicone, perlite, synthetic fluorophlogopite, nylon-12, isopropyl lauroyl sarcosinate, diisopropyl sebacate, disteardimonium hectorite, HDI/trimethylol hexyllactone crosspolymer, bis-PEG/PPG-14/14 dimethicone, magnesium sulfate, aluminum hydroxide, phenoxyethanol, disodium stearyl glutamate, hydrogen dimethicone, dipentaerythrityl tetrahydroxystearate/tetraisostearate, fragrance, silica silylate, acrylonitrile/methyl methacrylate/vinylidene chloride copolymer, tocopherol, hexyl cinnamal, silica, isobutane, benzyl salicylate, linalool, alpha-isomethyl ionone, benzyl alcohol, BHT, citronellol, may contain: titanium dioxide, iron oxides, ferric ammonium ferrocyanide

## Questions or comments?

1-800-322-2036

Monday - Friday

(10 a.m. - 5 p.m. EST)



UP TO 24HR  
**24HR**  
BREATHABLE  
TEXTURE  
RESPIRABLE

**480**

L'ORÉAL  
PARIS

**INFALLIBLE**  
**UP TO 24H FRESH WEAR**  
FOUNDATION

SUNSCREEN  
BROAD SPECTRUM SPF 25

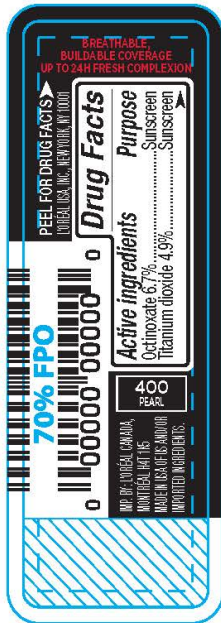






P1

Front



P3

Front of Mid Ply 1



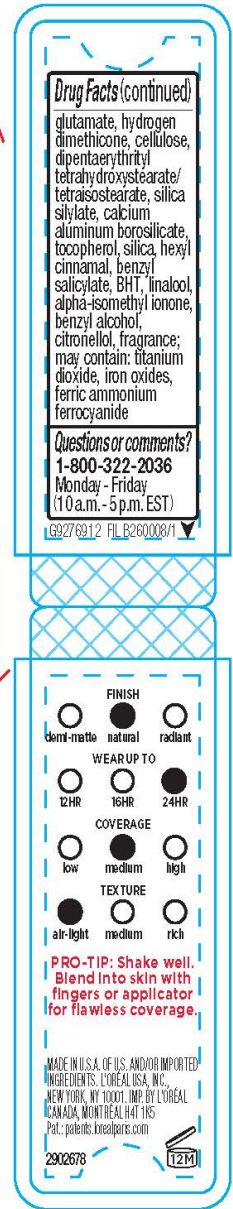
P5

Front of Mid Ply 2



P7

Bottom



P2

Back of Front

**Drug Facts (continued):**

**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 using
- 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.**

P4

Back of Mid Ply 1

**Drug Facts (continued):**

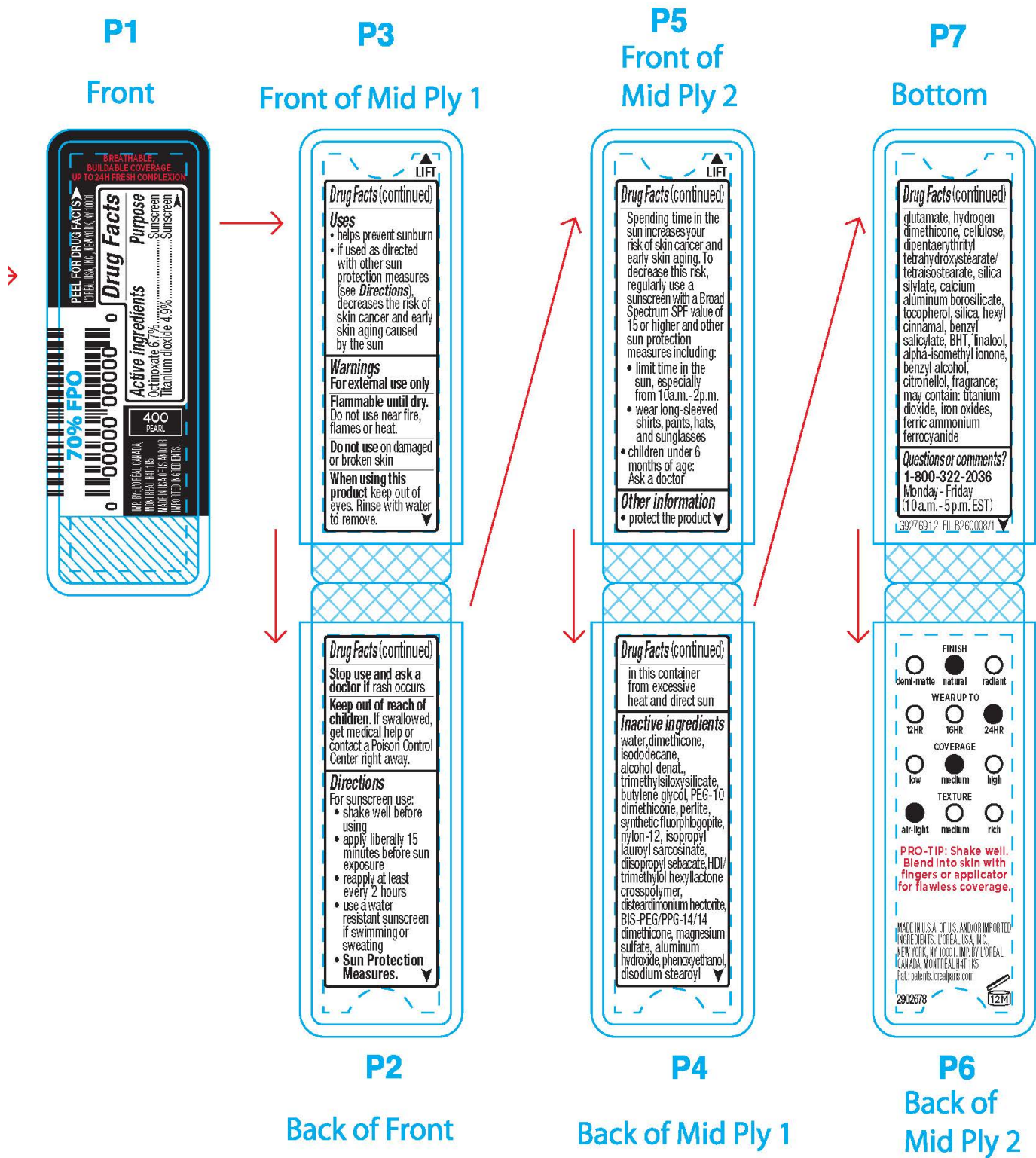
in this container from excessive heat and direct sun

**Inactive ingredients:** water, dimethicone, isododecane, alcohol denat., trimethylsiloxysilicate, butylene glycol, PEG-10 dimethicone, perlite, synthetic fluorophlogopite, nylon-12, isopropyl lauroyl sarcosinate, diisopropyl sebacate, HDI/trimethylol hexyl lactone crosspolymer, disteardimonium hectorite, BIS-PEG/PPG-14/14 dimethicone, magnesium sulfate, aluminum hydroxide, phenoxethanol, disodium stearoyl

P6

Back of Mid Ply 2





## LOREAL PARIS INFALLIBLE UP TO 24 H FRESH WEAR FOUNDATION BROAD SPECTRUM SPF 25 SUNSCREEN

octinoxate and titanium dioxide liquid

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-009
Route of Administration	TOPICAL		



Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	67 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	36 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8)</b> (UNII: 5041RX63GN)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>PERLITE</b> (UNII: 0SG101ZGK9)	
<b>MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE</b> (UNII: YK3DC63Y5M)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>ISOPROPYL LAUROYL SARCOSINATE</b> (UNII: LYR06W430J)	
<b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER</b> (UNII: WB5K9Y35Y9)	
<b>BIS-PEG/PPG-14/14 DIMETHICONE</b> (UNII: X2I70H0QJE)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>HYDROGEN DIMETHICONE (13 CST)</b> (UNII: 4QGR4P2YOI)	
<b>DIPENTAERYTHRITYL TETRAHYDROXYSTEARATE/TETRAISOSTEARATE</b> (UNII: 230K0823CE)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>.ALPHA.-HEXYLCINNAMALDEHYDE</b> (UNII: 7X6O37OK2I)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ISOBUTANE</b> (UNII: BXR49TP611)	
<b>BENZYL SALICYLATE</b> (UNII: WAO5MNK9TU)	
<b>LINALOOL, (+/-)-</b> (UNII: D81QY6I88E)	
<b>ISOMETHYL-.ALPHA.-IONONE</b> (UNII: 9XP4LC555B)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>.BETA.-CITRONELLOL, (R)-</b> (UNII: P01OUT964K)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>FERRIC AMMONIUM FERROCYANIDE</b> (UNII: 9R0NVI936I)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC 40067-000	30 mL in 1 BOTTLE, Type 0, Not a Combination		

1	NDC:49967-009-01	30 mL in 1 BOTTLE; Type O: Not a Combination Product	10/01/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		10/01/2018	

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

## Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		624244349	manufacture(49967-009)

Revised: 12/2023

L'Oreal USA Products Inc