

**LOREAL PARIS INFALLIBLE PROGLOW BROAD SPECTRUM SPF 15 SUNSCREEN-  
octinoxate liquid  
L'Oreal USA Products Inc**

-----

**Drug Facts**

**Active ingredients**

Octinoxate 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

**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, cyclopentasiloxane, alcohol denat., phenyl trimethicone, glycerin, PEG-10 dimethicone, bis-PEG/PPG-14/14 dimethicone, dimethicone, magnesium sulfate, ethylhexyl hydroxystearate, talc, silica, PEG/PPG/polybutylene glycol-8/5/3 glycerin, disodium stearyl glutamate, dimethicone/polyglycerin-3 crosspolymer, polymethyl methacrylate, tocopheryl acetate, aluminum hydroxide, magnesium stearate, silica silylate, dipropylene glycol, alumina, BHT, sodium citrate, tocopherol, isopropyl alcohol; may contain: titanium dioxide, iron oxides, bismuth oxychloride

## Questions or comments?

1-800-322-2036

Monday - Friday

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



UP TO

**24HR**  
FOUNDATION

**INFALLIBLE**  
**PRO-GLOW**

**202**  
CREAMY NATURAL

**OCTINOXATE SUNSCREEN**  
BROAD SPECTRUM SPF 15

RADIANT FINISH  
NORMAL/DRY SKIN  
HYDRATING

1.0 FL. OZ./30 ml



**L'ORÉAL®**  
PARIS

UP TO

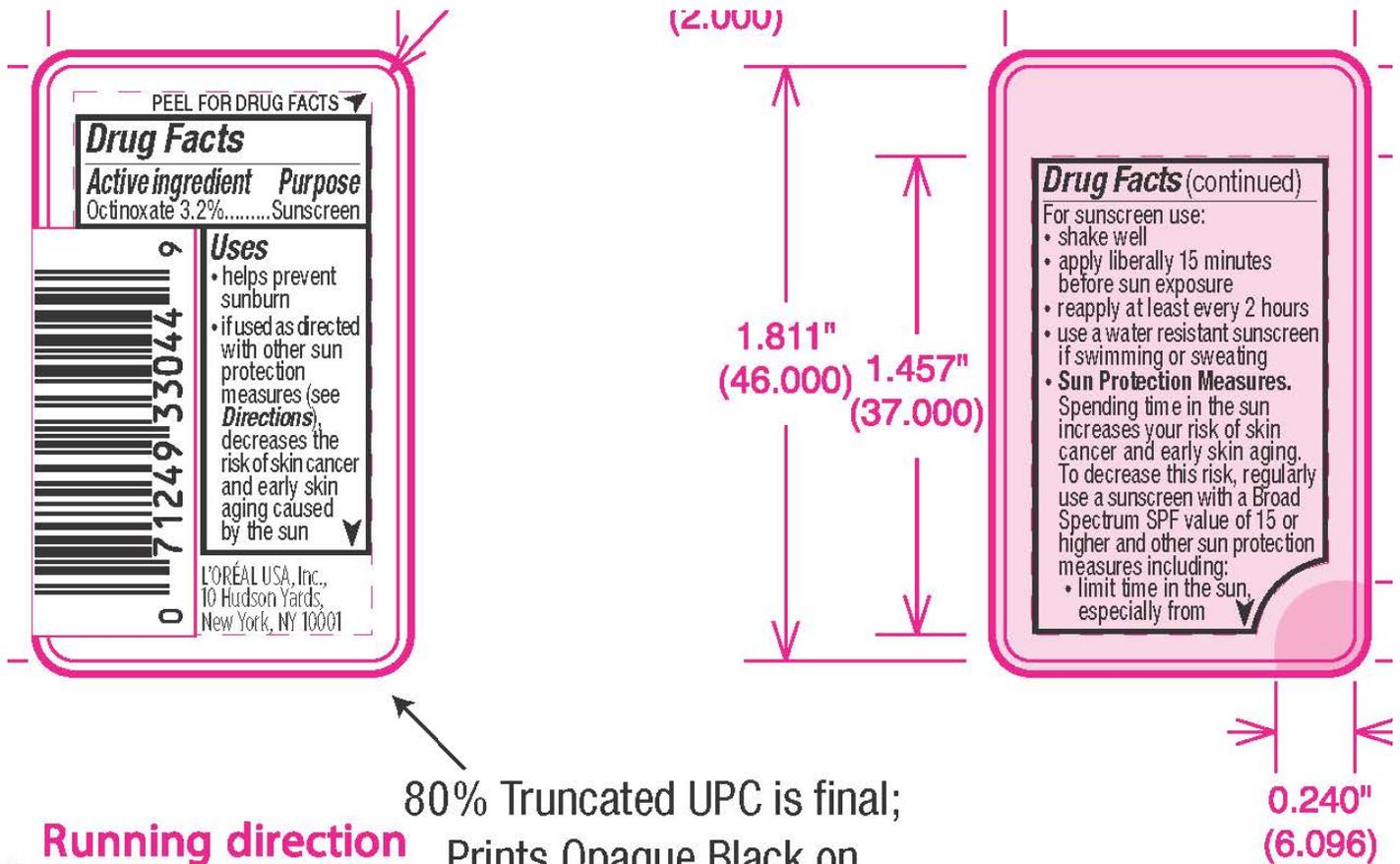
**24HR**  
FOUNDATION

**INFALLIBLE**  
**PRO-GLOW**

**202**  
CREAMY NATURAL

OCTINOXATE SUNSCREEN  
BROAD SPECTRUM SPF 15

RADIANT FINISH  
NORMAL/DRY SKIN  
HYDRATING

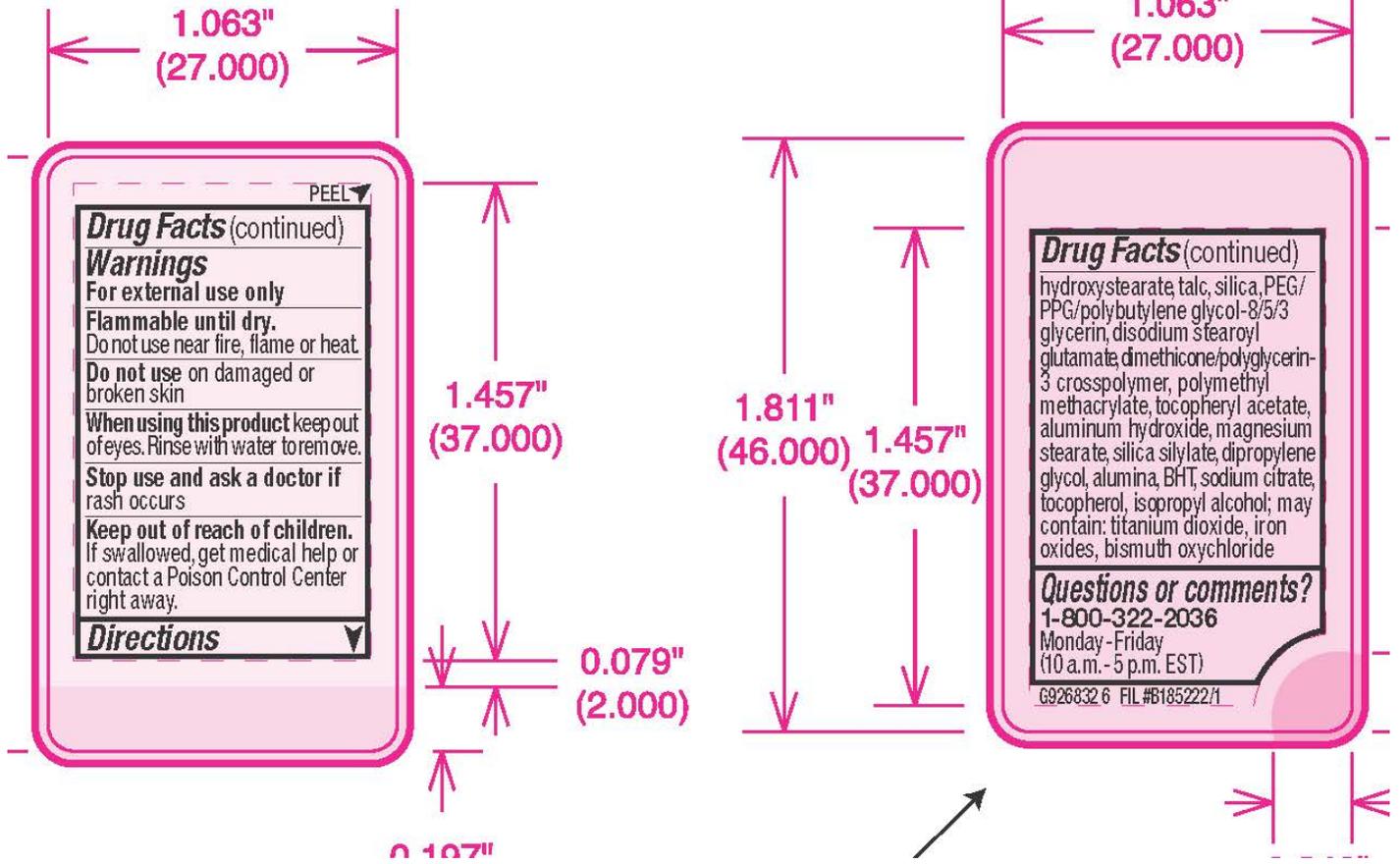


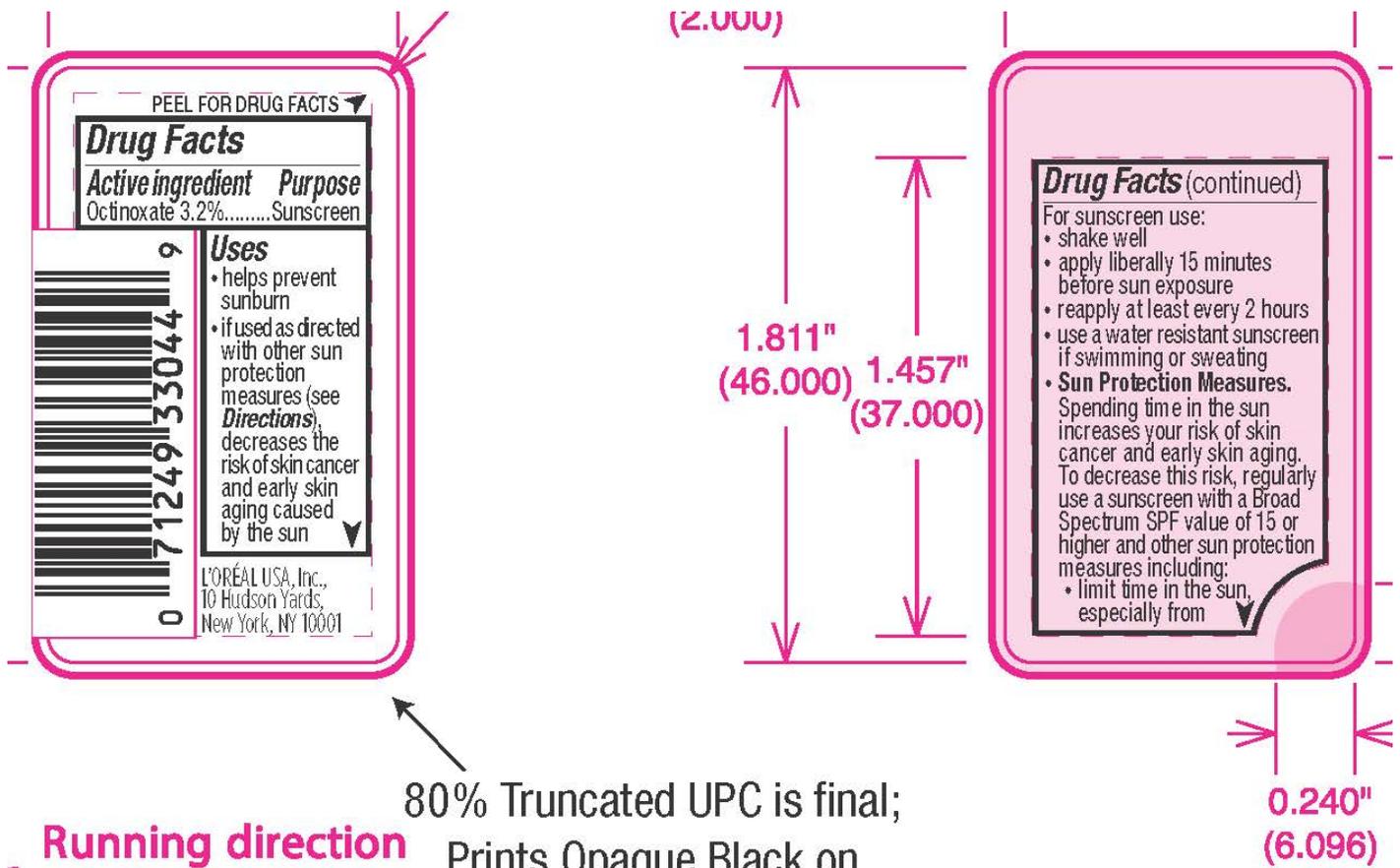
**Running direction**

80% Truncated UPC is final;  
Prints Opaque Black on  
White Label substrate;  
bars bleed off edge

middle layer front side

middle layer back side

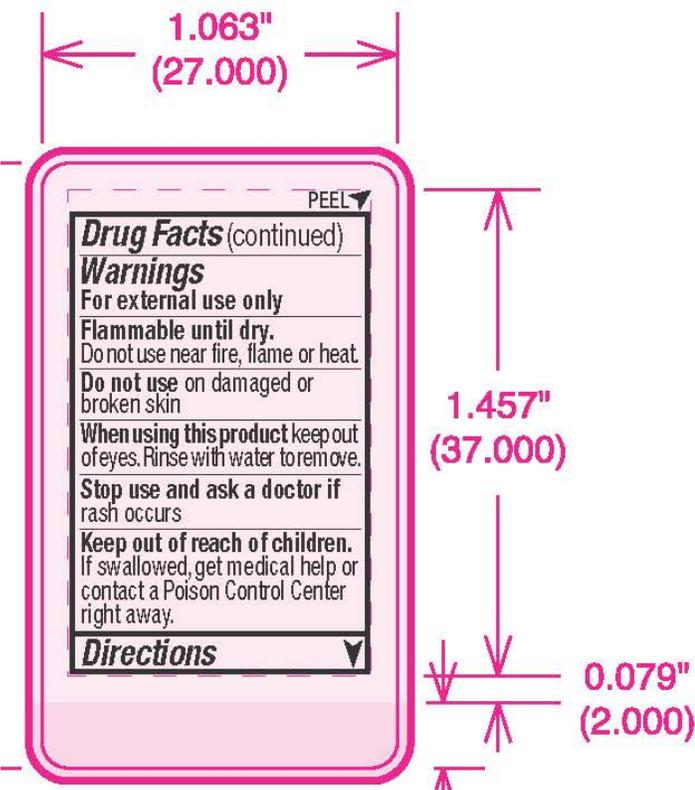




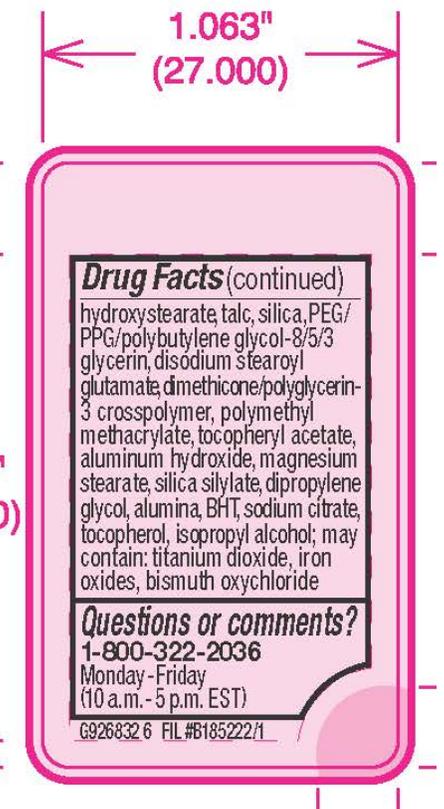
**Running direction** Prints Opaque Black on White Label substrate; bars bleed off edge

80% Truncated UPC is final;

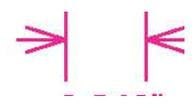
middle layer front side



middle layer back side



↑  
0.107"



L'ORÉAL USA, Inc., 10 Hudson Yards,  
New York, NY 10001 • 1.0 FL. OZ./30 ml

**Drug Facts** (continued)

- 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., phenyl trimethicone, glycerin, PEG-10 dimethicone, BIS-PEG/PPG-14/14 dimethicone, dimethicone, magnesium sulfate, ethylhexyl ▼

L'ORÉAL USA, Inc., 10 Hudson Yards,  
New York, NY 10001 • 1.0 FL. OZ./30 ml

### **Drug Facts** (continued)

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., phenyl trimethicone, glycerin, PEG-10 dimethicone, BIS-PEG/PPG-14/14 dimethicone, dimethicone, magnesium sulfate, ethylhexyl ▼

## **LOREAL PARIS INFALLIBLE PROGLOW BROAD SPECTRUM SPF 15 SUNSCREEN**

octinoxate liquid

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-043
<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	32 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>PHENYL TRIMETHICONE</b> (UNII: DR0K5NOJ4R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PEG-14 DIMETHICONE</b> (UNII: G7DL1Y4G26)	
<b>BIS-PEG/PPG-14/14 DIMETHICONE</b> (UNII: X2I70H0QJE)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>ETHYLHEXYL HYDROXYSTEARATE</b> (UNII: B7I80BVV5E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>BISMUTH OXYCHLORIDE</b> (UNII: 4ZR792I587)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-043-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2016	02/26/2016
2	NDC:49967-043-02	30 mL in 1 TUBE; Type 0: Not a Combination Product	02/26/2016	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/26/2016	

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

## Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA Products, Inc.		624244349	manufacture(49967-043) , pack(49967-043)

Revised: 12/2023

L'Oreal USA Products Inc