

**SKINCEUTICALS PHYSICAL EYE UV DEFENSE SUNSCREEN- titanium dioxide and zinc oxide lotion**  
**L'Oreal USA Products Inc**

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**Drug Facts**

**Active ingredients**

Titanium dioxide 9%

Zinc oxide 4%

**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**

dimethicone, C12-15 alkyl benzoate, triethylhexanoin, isohexadecane, talc, hydrogenated jojoba oil, dimethicone crosspolymer, styrene/acrylates copolymer, C30-45 alkyldimethylsilyl polypropylsilsesquioxane, dimethicone/vinyl dimethicone crosspolymer aluminum stearate, alumina, polyhydroxystearic acid, iron oxides, phenoxyethanol, silica silylate, PEG-8 laurate, triethoxycaprylylsilane, 2-oleamido-1,3-octadecanediol, disodium stearyl glutamate, paraffin, aluminum hydroxide

### **Questions or comments?**

Call **1-800-811-1660**

Monday - Friday

(9 a.m. - 5 p.m. CST)

**Drug Facts**

(continued)

**Inactive Ingredients**

dimethicone, C12-15 alkyl benzoate, triethylhexanoin, isohexadecane, talc, hydrogenated jojoba oil, dimethicone copolymer, styrene/acrylates copolymer, C30-45 alkyl dimethylsilyl polypropylsilsesquioxane, dimethicone/vinyl dimethicone copolymer, aluminum stearate, alumina, polyhydroxystearic acid, iron oxides, phenoxethanol, silica silylate, PEG-8 laurate, triethoxycaprylylsilane, 2-oleamido-1,3-octadecanediol, disodium stearoyl glutamate, paraffin, aluminum hydroxide

**Questions or comments?**

Call 1-800-811-1680  
Monday-Friday  
(9 a.m. - 5 p.m. CST)

050349 15  
(CODE FILL: 0189576/1)

**SKINCEUTICALS**

Manufactured for and distributed by  
SkinCeuticals LLC, Garland, TX 75041  
Made in USA www.skinceuticals.com

PROTECT

SKINCEUTICALS

**PHYSICAL EYE  
UV DEFENSE  
SUNSCREEN**

**BROAD SPECTRUM  
SPF 50**

NON-MIGRATING  
PROTECTIVE EYE BASE  
TO ENHANCE SKIN TONE  
TESTED POST-PROCEDURE

10 ml / 0.3 fl oz

SKINCEUTICALS



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81695 7110

7854821





**Drug Facts**  
(continued)

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Monday-Friday  
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050349 15  
(CODE FLL: D1895761)

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**SKINCEUTICALS PHYSICAL EYE UV DEFENSE SUNSCREEN**

titanium dioxide and zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-050
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	90 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	40 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>HYDROGENATED JOJOBA OIL</b> (UNII: 7F674YQ5SO)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>9-OCTADECENAMIDE, N-(2-HYDROXY-1-(HYDROXYMETHYL)HEPTADECYL)-, (9Z)-</b> (UNII: 30D478BUNR)	
<b>DISODIUM STEAROYL GLUTAMATE</b> (UNII: 45ASM2L11M)	
<b>PARAFFIN</b> (UNII: I9O0E3H2ZE)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-050-01	1 in 1 CARTON	04/18/2014	07/27/2026
1		10 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-050-02	0.15 mL in 1 PACKET; Type 0: Not a Combination Product	04/18/2014	07/27/2026

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/18/2014	07/27/2026

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

## Establishment

Name	Address	ID/FEI	Business Operations
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Goodier Cosmetics LP		007317209	manufacture(49967-050)
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## Establishment

Name	Address	ID/FEI	Business Operations
Beauty Manufacturing Solutions Corp.		783200723	manufacture(49967-050)

Revised: 12/2023

L'Oreal USA Products Inc