

**SKINCEUTICALS PHYSICAL UV DEFENSE BROAD SPECTRUM SPF 30  
SUNSCREEN- titanium dioxide and zinc oxide cream  
L'Oreal USA Products Inc**

-----  
**Drug Facts**

**Active ingredients**

Titanium dioxide 5%

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**

- shake well before 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

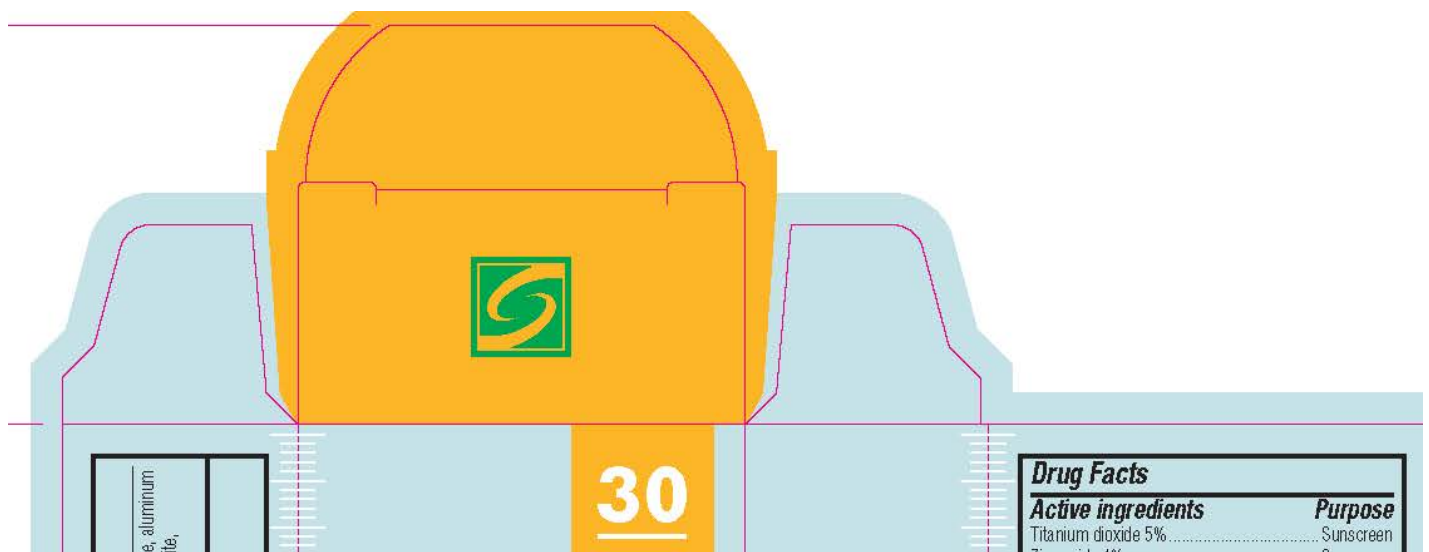
### Inactive ingredients

water, glycerin, c12-15 alkyl benzoate, dimethicone, butyloctyl salicylate, phenethyl benzoate, triethylhexanoin, isohexadecane, styrene/acrylates copolymer, stearyl dimethicone, butyrospermum parkii (shea) butter, isododecane, polyglyceryl-4 isostearate, talc, dimethicone/polyglycerin-3 crosspolymer, nylon-12, pentylene glycol, lauryl PEG-9 polydimethylsiloxylethyl dimethicone, aluminum stearate, phenoxyethanol, alumina, polyhydroxystearic acid, magnesium sulfate, caprylyl glycol, PEG-8 laurate, disteardimonium hectorite, triethoxycaprylylsilane, tocopherol, propylene carbonate, artemia extract, benzoic acid, dipropylene glycol, sodium hyaluronate

### Questions or comments?

Call 1-800-811-1660

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



**PROTECT**

**Drug Facts (continued)**

isostearate, talc, dimethicone/polyglycerin-3 crosspolymer, nylon-12, pentylene glycol, lauryl PEG-9 polydimethylsilyloxyethyl dimethicon  
 stearate, phenoxyethanol, alumina, polyhydroxystearic acid, magnesium sulfate, caprylyl glycol, PEG-8 laurate, disteardimonium hector  
 triethoxycaprylylsilane, tocopherol, propylene carbonate, artemia extract, benzoic acid, dipropylene glycol, sodium hyaluronate

**Questions or comments?**

Call 1-800-811-1660 Monday – Friday (9 a.m. – 5 p.m. CST)

868193 38 (CODE FJL - 052516V2)  
 Tested post peel  
**SKINCEUTICALS®**  
 SkinCeuticals LLC, Dallas, TX 75241  
 Made in USA of US and/or Imported  
 Ingredients: www.skinceuticals.com

**SKINCEUTICALS**  
**PHYSICAL UV DEFENSE SUNSCREEN**

BROAD SPECTRUM  
 SPF 30

PROTECTS SKIN BARRIER  
 TESTED POST PROCEDURE  
 100% MINERAL FILTERS  
 CREAM

50 ml / 1.7 fl oz

SKINCEUTICALS



**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:  
 • shake well before 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, glycerin, C12-15 alkyl benzoate, dimethicone, butyloctyl salicylate, phenethyl benzoate, triethylhexanoin, isohexadecane, styrene/acrylates copolymer, stearyl dimethicone, butyrospermum parkii (shea) butter, isododecane, polyglyceryl-4

AREA FOR DAY LOT CODE

8 83140 02472 9

8612621697988

0519

MIX Packaging FSC® C018066

**SKINCEUTICALS PHYSICAL UV DEFENSE BROAD SPECTRUM SPF 30 SUNSCREEN**

titanium dioxide and zinc oxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-472
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	50 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	40 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)	
<b>STEARYL TRISILOXANE</b> (UNII: 796MG354ZZ)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>LAURYL PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: 25G622K2RA)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>ARNICA MONTANA</b> (UNII: O80TY208ZW)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>DIPROPYLENE GLYCOL</b> (UNII: E107L85C40)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-472-01	1 in 1 CARTON	01/01/2012	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-472-02	4 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2012	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/01/2012	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetic Essence, LLC		032565959	manufacture(49967-472)

## Establishment

Name	Address	ID/FEI	Business Operations
Goodier Cosmetics LP		007317209	manufacture(49967-472)

Revised: 12/2023

L'Oreal USA Products Inc