

**SKINCEUTICALS PHYSICAL MATTE UV DEFENSE BROAD SPECTRUM SPF 50
SUNSCREEN- titanium dioxide and zinc oxide lotion
L'Oreal USA Products Inc**

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

- apply liberally 15 minutes before sun exposure

- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **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, dicaprylyl ether, dimethicone/vinyl dimethicone crosspolymer, talc, triethylhexanoin, isohexadecane, styrene/acrylates copolymer, hydrogenated jojoba oil, aluminum hydroxide, stearic acid, aluminum stearate, iron oxides, silica silylate, alumina, polyhydroxystearic acid, PEG-8 laureth, tocopherol, water, diethylhexyl syringylidenemalonate, laureth-4, disodium stearyl glutamate, cassia alata leaf extract, maltodextrin, caprylic/capric triglyceride

Questions or comments?

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

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



dimethicone crosspolymer,
aluminum stearate,
PEG-8 laurate,
triethoxycaprylylsilane,
silica silylate,
2-oleamido-1,3-octadecanediol,
alumina, aluminum
hydroxide, iron oxides,
disodium stearyl glutamate,
polyhydroxystearic acid

Questions or comments?

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

858387 11
(CODE F.I.L.: D172511/1)



SKINCEUTICALS

PHYSICAL MATTE
UV DEFENSE
SUNSCREEN

BROAD SPECTRUM
SPF 50

ABSORBS OIL

100% MINERAL FILTERS
TINTED MOUSSE

30 ml / 1 fl oz

SKINCEUTICALS
SkinCeuticals LLC, Dallas, TX 75241
Made in USA of US and/or Imported
Ingredients www.skinceuticals.com

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:

- 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, talc, dicaprylyl ether, triethylhexanoin, isohexadecane, dimethicone ▶

[7]

3612621 698022

0519

AREA FOR
DAY LOT CODE



3 606000 419292



MIX
Packaging



50

PROTECT

Drug Facts (continued)

crosspolymer, styrene/acrylates copolymer, hydrogenated jojoba oil, dimethicone/vinyl dimethicone crosspolymer, aluminum stearate, PEG-8 laurate, triethoxycaprylylsilane, silica silylate, 2-oleamido-1,3-octadecanediol, alumina, aluminum hydroxide, iron oxides, disodium stearyl glutamate, polyhydroxystearic acid

Questions or comments?

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

85838711
(CODE F.I.L.: D172511/1)



SKINCEUTICALS

PHYSICAL MATTE
UV DEFENSE
SUNSCREEN

BROAD SPECTRUM
SPF 50

ABSORBS OIL

100% MINERAL FILTERS
TINTED MOUSSE

30 ml / 1 fl oz

SKINCEUTICALS
SkinCeuticals LLC, Dallas, TX 75241
Made in USA of US and/or Imported
Ingredients www.skinceuticals.com

SKINCEUTICALS



Drug Facts

Active ingredients	Purpose
Titanium dioxide 9%	Sunscreen
Zinc oxide 4%	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, talc, dicaprylyl ether, triethylhexanoin, isohexadecane, dimethicone

[7]

3612621 698022

0519

AREA FOR
DAY LOT CODE





SKINCEUTICALS PHYSICAL MATTE UV DEFENSE BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-929
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TALC (UNII: 7SEV7J4R1U)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
HYDROGENATED JOJOBA OIL (UNII: 7F674YQ5S0)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (HARD PARTICLE) (UNII: H895X08VNO)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
2-OLEAMIDO-1,3,4-OCTADECATRIYL PROLINATE (UNII: 690VHX6497)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-929-01	1 in 1 CARTON	03/01/2015	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-929-02	1 in 1 CARTON	03/01/2015	
2		4 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/01/2015	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Goodier Cosmetics LP		007317209	manufacture(49967-929)

Revised: 12/2023

L'Oreal USA Products Inc