

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS 50 TINTED
MINERAL FACE BROAD SPECTRUM SPF 50 SUNSCREEN- titanium dioxide lotion
L'Oreal USA Products Inc**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient

Titanium dioxide 11%

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:

- shake well before use
- apply generously 15 minutes before sun exposure
- reapply:
 - after 40 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

water, isododecane, C12-15 alkyl benzoate, dimethicone, undecane, triethylhexanoin, isohexadecane, styrene/acrylates copolymer, nylon-12, caprylyl methicone, butyloctyl salicylate, phenethyl benzoate, silica, tridecane, dicaprylyl carbonate, dicaprylyl ether, talc, dimethicone/PEG-10/15 crosspolymer, aluminum stearate, pentylene glycol, PEG-9 polydimethylsiloxylethyl dimethicone, iron oxides, alumina, polyhydroxystearic acid, phenoxyethanol, magnesium sulfate, propylene glycol, caprylyl glycol, aluminum hydroxide, PEG-8 laurate, stearic acid, disteardimonium hectorite, diethylhexyl syringlidenemalonate, tocopherol, propylene carbonate, cassia alata leaf extract, maltodextrin, benzoic acid, disodium stearyl glutamate, PEG-9

Questions or comments?

1-888-577-5226 1-888-LRP LABO

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

ANTHELIOS 50
MINERAL

FACE
50

FACE
50

SUNSCREEN

LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

BROAD SPECTRUM
SPF50

TINTED

ANTHELIOS 50
MINERAL

Avec de l'eau thermale de La Roche-Posay

ULTRA LIGHT SUNSCREEN FLUID
100% mineral UV filter system
Matte finish. Universal tint

Advanced Protection
with **CELL-OX SHIELD™**
UVA/UVB + ANTIOXIDANT



WATER RESISTANT (40 MINUTES)
Fragrance-free. Paraben-free
Tested on sensitive skin

1.7 FL OZ - 50 ml

ANTHELIOS 50 MINERAL
sunscreen with CELL-OX
SHIELD™:

A unique patent pending
combination of a mineral sun
filter with powerful
antioxidants in a fluid texture
to protect your skin down to the
cellular level¹.

Properties:

- 100% mineral UV filter system.
- An optimized blend of titanium dioxide to offer broad-spectrum protection with demonstrated efficacy against UVA rays.
- A patent pending dispersion technology to help assure uniform protection.

- Powerful antioxidant complex.
- Senne Alata, a tropical leaf extract known to defend skin cells¹.

- Additional antioxidants to help protect skin from environmental aggressors.

- Breakthrough texture: Fast-absorbing fluid, tinted for a natural glow. Universal tint matches most every skin tone for a uniform complexion. Skin feels hydrated with a matte finish.

Results: Decreases the risk of skin cancer and early skin aging caused by the sun if used as directed with other sun protection measures (see *Directions*).

Dermatological safety: ANTHELIOS 50 sunscreen has been rigorously tested and formulated for optimal skin tolerance.

WATER RESISTANT
(40 MINUTES)
FRAGRANCE-FREE
PARABEN-FREE
NON-COMEDOGENIC
ALLERGY TESTED
DERMATOLOGIST TESTED
TESTED ON SENSITIVE SKIN

¹ upper layers of skin



Made in France

Distributed by La Roche-Posay LLC,
New York, NY 10001

La Roche-Posay
Laboratoire Dermatologique
CAJ 86276 La Roche-Posay, France
TBA 75000 PARIS ET 051EN CEDEX FR
www.laroche-posay.com

Every day, dermatologists observe the severe skin damage caused by UVA and UVB ray exposure.

UVB rays mainly cause **Burning**. They are stopped by the epidermis. They cause tanning and are mainly responsible for sunburn. SPF or "Sun Protection Factor" is the degree of protection a sunscreen offers against UVB rays.

UVA rays mainly cause **Aging or Sun Allergies**. They penetrate deeper into the skin than UVB rays and can reach into the dermis. UVA rays directly contribute to skin aging (wrinkles, sagging, dark spots) and are the #1 cause of sun intolerances (allergies).

Both UVA and UVB rays have been proven to cause damage to skin cells, including DNA, and to weaken the immune system. This damage can potentially lead to the development of skin cancer.

A pioneer in UV protection research for over 15 years, La Roche-Posay, with ANTHELIOS, is trusted by dermatologists worldwide for its advanced formulations in UVA protection.

To learn more about La Roche-Posay products or to get sun safe tips, visit www.laroche-posay.us or check our Facebook [@facebook.com/LaRochePosayUSA](https://www.facebook.com/LaRochePosayUSA)



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US Pat. Pending

Code F.I.L.: D176222/1

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LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS 50 TINTED MINERAL FACE BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49967-020

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	110 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISODODECANE (UNII: A8289P68Y2)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
UNDECANE (UNII: JV0QT00NUE)	
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
NYLON-12 (UNII: 446U8J075B)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIDECANE (UNII: A3LZF0L939)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
TALC (UNII: 7SEV7J4R1U)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ALUMINUM OXIDE (UNII: LM26O6933)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SENNA ALATA LEAF (UNII: 4BXR6YZN92)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-020-01	1 in 1 CARTON	01/30/2017	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49967-020-02	1 in 1 CARTON	01/30/2017	
2		3 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-020-03	1 in 1 CARTON	01/30/2017	
3		125 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/30/2017	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(49967-020) , analysis(49967-020)

Establishment

Name	Address	ID/FEI	Business Operations
Interspray		364829903	pack(49967-020)

Revised: 2/2017

L'Oreal USA Products Inc