

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS 50 MINERAL  
ULTRA LIGHT SUNSCREEN- titanium dioxide and zinc oxide lotion  
L'Oreal USA Products Inc**

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**Drug Facts**

**Active ingredients**

Titanium Dioxide 6%

Zinc Oxide 5%

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

### **Questions or comments?**

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

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

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 sun 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](http://www.laroche-posay.us) or check our Facebook: [@facebook.com/LaRochePosayUSA](https://www.facebook.com/LaRochePosayUSA).

FACE  
**50**

SUNSCREEN

**LA ROCHE-POSAY**  
LABORATOIRE DERMATOLOGIQUE

BROAD SPECTRUM  
SPF50

**ANTHELIOS 50**  
MINERAL

Avec de l'eau thermale de La Roche-Posay

ULTRA LIGHT SUNSCREEN FLUID  
100% mineral UV filter system  
Matte finish, non-whitening

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 mineral sun filters with powerful antioxidants in a fluid texture to protect your skin down to the cellular level!

**Properties:**

**100% mineral UV filter system**

- An optimized blend of titanium dioxide and zinc oxide to offer broad-spectrum protection with demonstrated effectiveness against UVA rays.

- A patent pending dispersion technology helps assure uniform protection.

**Powerful antioxidant complex**

- Senha Alata, a tropical leaf extract known to defend skin cells!

- Additional antioxidants to help protect skin from environmental aggressors.

**Breaththrough texture**

Fast absorbing, non-whitening texture. Skin feels hydrated with a matte finish. Suitable for use under make-up.

**Results:** 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.

**Dermatological safety:**

ANTHELIOS 50 sunscreen has been rigorously formulated for optimal skin tolerance.

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

upper layers of skin



Distributed by La Roche-Posay LLC,  
New York, NY 10017

La Roche-Posay  
Laboratoire Pharmaceutique  
96270 La Roche-Posay France  
TSA 1007 F 92467 ASNIERES CEDEX  
[www.laroche-posay.com](http://www.laroche-posay.com)

**Drug Facts**

Active ingredients	Purpose
Titanium dioxide 6%	Sunscreen
Zinc oxide 5%	Sunscreen

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**Other information**

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**Inactive ingredients**

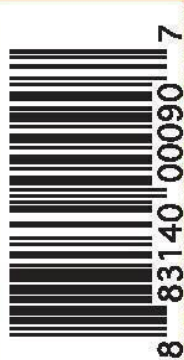
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858238  
US Pat. Pending

Code F.I.L.: D53728/1



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SUNSCREEN

16.25

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LABORATOIRE DERMATOLOGIQUE

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UVA/UVB + ANTIOXIDANT

SHAKE  
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Tested on sensitive skin

14.75

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upper layers of skin

Made in France

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# LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS 50 MINERAL ULTRA LIGHT SUNSCREEN

titanium dioxide and zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49967-907
<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	60 mg in 1 mL
<b>Zinc oxide</b> (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	50 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>UNDECANE</b> (UNII: JVOQT00NUE)	
<b>TRIETHYLHEXANOIN</b> (UNII: 7K3W1BIU6K)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>NYLON-12</b> (UNII: 446U8J075B)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>PHENETHYL BENZOATE</b> (UNII: 0C143929GK)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (MW 500000)</b> (UNII: 5Z4DPO246A)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TRIDECANE</b> (UNII: A3LZF0L939)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>DICAPRYLYL ETHER</b> (UNII: 77JZM5516Z)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>ALUMINUM STEARATE</b> (UNII: U6XF9NP8HM)	
<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
<b>PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE</b> (UNII: TYP81E471F)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>PEG-8 LAURATE</b> (UNII: 762O8IWA10)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>BENZOIC ACID</b> (UNII: 8SKN0B0MIM)	
<b>POLYETHYLENE GLYCOL 450</b> (UNII: 5IRA46LB71)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-907-01	1 in 1 CARTON	07/01/2011	
1		50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:49967-	1 in 1 CARTON	07/01/2011	07/01/2011

1	907-02	1 in 1 CARTON	07/01/2011	07/01/2011
2		3 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-907-03	1 in 1 CARTON	12/02/2019	
3		5 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	07/01/2011	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(49967-907) , analysis(49967-907) , pack(49967-907)

## Establishment

Name	Address	ID/FEI	Business Operations
Interspray		364829903	pack(49967-907)

Revised: 12/2023

L'Oreal USA Products Inc