

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS 50 DAILY  
ANTIAGING PRIMER WITH SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene  
and oxybenzone 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.*

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**Drug Facts**

**Active ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

Oxybenzone 6%

**Uses**

- helps prevent sunburn
- if used as directed (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 generously 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

## **Purpose**

Sunscreen

## **Other information**

- protect the product in this container from excessive heat and direct sun

## **Inactive ingredients**

dimethicone, C12-15 alkyl benzoate, talc, diisopropyl sebacate, silica, silica silylate, glycerin, trimethylsiloxysilicate, dimethicone crosspolymer, water, diethylhexyl syringylidenemalonate, cassia alata leaf extract, maltodextrin

## **Questions or comments?**

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

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

Dermatologists know that: **UVA rays** are responsible for more than **80%** of skin aging (fine lines, wrinkles, sagging, dark spots) and are the main cause of sun intolerances.

All year-long, even in cloudy weather, in the city or through glass, UVA rays penetrate the skin down to the dermis layer. This is why dermatologists recommend using a daily, broad spectrum UVA/UVB product to help prevent early skin aging and sun reactions.

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.

Dermatological safety: ANTHELIOS 50 Daily Anti-Aging Primer with sunscreen has been formulated and rigorously tested for optimal skin tolerance.

FRAGRANCE-FREE  
NON-COMEDOGENIC  
ALLERGY TESTED  
DERMATOLOGIST TESTED  
TESTED ON SENSITIVE SKIN



Made in USA  
1543113

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

La Roche-Posay  
Laboratoire Pharmaceutique  
86270 La Roche-Posay France  
TSA 10097 F 92667 ASNIERES CEDEX  
www.laroche-posay.com

DAILY  
**50**  
SUNSCREEN

LA ROCHE-POSAY  
LABORATOIRE DERMATOLOGIQUE

BROAD SPECTRUM  
SPF50

**ANTHELIOS 50**

DAILY ANTI-AGING PRIMER  
with SUNSCREEN

Instant optical correction  
of fine lines, wrinkles and pores

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

Non comedogenic  
Fragrance-free. Paraben-free  
Tested on sensitive skin

1.35 FLOZ - 40 ml

**BREAKTHROUGH INNOVATION**

For the 1<sup>st</sup> time, ANTHELIOS 50 Daily Anti-Aging Primer with sunscreen combines broad spectrum UVA/UVB protection and powerful antioxidants in a primer that provides a blurring-effect on skin. This innovative skincare provides instant optical correction of signs of aging and daily prevention of aging caused by the sun.

**Properties:**

1. **Instant correction of signs of skin aging**  
Colorless, lightweight texture fills-in and smoothes imperfections (fine lines, wrinkles, pores) for an even complexion and an instantly younger-looking skin. Its formula is enriched with absorbing powders to mattify skin and eliminate excess sebum in combination and oily skin.

2. **Daily Anti-Aging UV + Antioxidant protection**  
- Advanced anti-aging filtering system

Protects from signs of skin aging caused by the sun thanks to a patented association of sunscreens for a daily broad-spectrum protection with advanced effectiveness against UVA rays, the main cause of skin aging.  
- **Powerful CELL-OX SHIELD™ antioxidant complex**  
With Senes Alata, a tropical leaf extract known to defend skin cells<sup>1</sup> for reinforced protection against UV-induced free radicals that accelerate skin aging process.

**Results:**

Skin is instantly younger-looking with a matte powdery finish. Imperfections visibly disappear. Day after day, skin is protected from signs of skin aging caused by the sun.

**For use:**

Apply each morning to clean face and neck.  
Easy to spray and non comedogenic, this primer does not clog pores. If used with other skincare, use as a last step in regimen.  
Can be used alone or under make-up. Creates a smooth skin surface for easier make-up glide and longer-lasting coverage.  
<sup>1</sup> upper layers of skin

**Drug Facts**

| Active ingredients | Purpose   |
|--------------------|-----------|
| Avobenzone 3%      | Sunscreen |
| Homosalate 10%     | Sunscreen |
| Octisalate 5%      | Sunscreen |
| Octocrylene 5%     | Sunscreen |
| Oxybenzone 6%      | Sunscreen |

**Uses**

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**Other information**

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**Inactive ingredients**

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669185 5  
US Pat. 5,867,765 and Pats. Pending

Code F.I.L.: D50828/1

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avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

**Product Information**

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:49967-095 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength       |
|--|-------------------|----------------|
| Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)   | Avobenzone        | 30 mg in 1 mL  |
| Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)   | Homosalate        | 100 mg in 1 mL |
| Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)   | Octisalate        | 50 mg in 1 mL  |
| Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM) | Octocrylene       | 50 mg in 1 mL  |
| Oxybenzone (UNII: 950OS7VE0Y) (Oxybenzone - UNII:950OS7VE0Y)   | Oxybenzone        | 60 mg in 1 mL  |

**Inactive Ingredients**

| Ingredient Name  | Strength |
|--|----------|
| DIMETHICONE (UNII: 92RU3N3Y1O)   |          |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)   |          |
| TALC (UNII: 7SEV7J4R1U)  |          |
| DIISOPROPYL SEBACATE (UNII: J8T3X564IH)  |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)   |          |
| GLYCERIN (UNII: PDC6A3C0OX)  |          |
| TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)                               |          |
| DIMETHICONE CROSSPOLYMER (45000 MPAS AT 12 % IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6) |          |
| WATER (UNII: 059QF0KO0R)   |          |
| DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)                                  |          |
| SENNA ALATA LEAF (UNII: 4BXR6YZN92)  |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)  |          |

### Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49967-095-01 | 1 in 1 CARTON                                      | 04/05/2012           |                    |
| 1 |                  | 40 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 not final | part352                                  | 04/05/2012           |                    |

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

### Establishment

| Name                     | Address | ID/FEI    | Business Operations    |
|--------------------------|---------|-----------|------------------------|
| L'Oreal USA Products Inc |         | 185931458 | manufacture(49967-095) |

Revised: 1/2020

L'Oreal USA Products Inc