

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS TINTED
MINERAL LIGHT FLUID SUNSCREEN BROAD SPECTRUM SPF 40 DEEP- titanium
dioxide and zinc oxide lotion
L'Oreal USA Products Inc**

Drug Facts

Active ingredients

Titanium dioxide 17%

Zinc oxide 8%

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
- apply to all skin exposed to the sun
- 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

iron oxides , isohexadecane, dimethicone, triethylhexanoin, c15-19 alkane, silica, c12-15 alkyl benzoate, caprylyl methicone, butyloctyl salicylate, aluminum stearate, dicaprylyl carbonate, dicaprylyl ether, talc, dimethicone/PEG-10/15 crosspolymer, alumina, polyhydroxystearic acid water, PEG-9 polydimethylsiloxyethyl dimethicone, pentylene glycol ● acrylates/dimethicone copolymer, aluminum hydroxide, stearic acid, phenoxyethanol, magnesium sulfate, caprylyl glycol, disodium stearyl glutamate, triethoxycaprylylsilane, disteardimonium hectorite, diethylhexyl syringylidenemalonate, tocopherol, propylene carbonate, cassia alata leaf extract, maltodextrin, dipropylene glycol, sodium citrate, caprylic/capric triglyceride

Questions or comments?

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

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

A PIONEER IN SUN PROTECTION RESEARCH FOR OVER 30 YEARS

Every day, dermatologists observe skin damage caused by UVA and UVB rays.

UVB rays mainly cause burning. 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 skin ageing and skin damage. They are mainly responsible for sunspots, wrinkles, and loss of skin elasticity. They are also responsible for the development of skin cancer.

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

La Roche-Posay is dedicated to providing photostable, broad spectrum protection through the award-winning CELL-OX SHIELD™ a unique combination of UV filters combined with antioxidants.

40 ANTHELIOS TINTED MINERAL DEEP



LA ROCHE-POSAY
LABORATOIRE DERMATOLOGIQUE

NEW ANTHELIOS TINTED MINERAL LIGHT FLUID SUNSCREEN

40 BROAD SPECTRUM SPF 40

FACE SUNSCREEN DEEP

100% MINERAL UV FILTERS

With CELL-OX SHIELD™ UVA / UVB Protection + Antioxidants

Tinted on sensitive skin. Fragrance-free.

1.7 FL. OZ. - 50 ml

ANTHELIOS TINTED MINERAL DEEP 40

Skintype: All skin types including sensitive skin.

Texture: Light Fluid

Application: Face

1. For Sensitive Skin. Ideal for all skin types including sensitive skin, and those who want a tinted sunscreen that provides a healthy glow with 100% mineral UV filters.

2. Lightweight Blendable Text. A gentle, mineral sunscreen with a non-greasy texture. The subtle, blendable tint with iron oxides creates a healthy glow while minimizing white cast, and is suitable for deeper pigmented skin. It provides a smooth base for makeup application. Leaves skin feeling hydrated with a dewy radiant finish. Shake well before use.

3. CELL-OX SHIELD TECHNOLOGY™. Mineral UV Filters, Titanium dioxide and zinc oxide deliver broad spectrum sunscreen protection. **Powered Antioxidant Protection** with green algae, a tropical leaf extract known to defend skin cells against damaging free radicals caused by the sun that can accelerate skin aging.

RESULT: This sunscreen 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).

Drug Facts

Active ingredients	Purpose
Titanium dioxide 11%	Sunscreen
Zinc oxide 1%	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 seek 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 occasional use:

- shake well before use
- apply generously 15 minutes before sun exposure
- apply to all skin exposed to the sun
- 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
- avoid sun if 6 months of age. Ask a doctor.

Other information

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

Inactive ingredients

iron oxides, hydrocarbons, dimethicone, triethylhexanoin, C15-18 alkanes, silica, C12-15 alkyl benzoate, caprylyl methacrylate, butylacetyl salicylate, aluminum stearate, dicaprylyl carbonate, dicaprylyl ether, bis, dimethicone/PS-10 crosspolymer, stearic acid, polydodecane, stearic acid, water, ppg-3 polydimethylsilyloxy dimethylsiloxane, polyethylene glycol, acrylate/dimethylacrylate copolymer, aluminum hydroxide, stearic acid, phenylethylalcohol, magnesium sulfate, caprylyl glycol, dimethyl glutarate, triethylcaprylylsilane, disodiumzinc undecylate, dimethylpropyl silyloxydimethylsiloxane, hexanediol, propylene carbonate, capryl alcohol, polybutene-1, polybutene-2, polybutene-3, polybutene-4, polybutene-5, polybutene-6, polybutene-7, polybutene-8, polybutene-9, polybutene-10, polybutene-11, polybutene-12, polybutene-13, polybutene-14, polybutene-15, polybutene-16, polybutene-17, polybutene-18, polybutene-19, polybutene-20, polybutene-21, polybutene-22, polybutene-23, polybutene-24, polybutene-25, polybutene-26, polybutene-27, polybutene-28, polybutene-29, polybutene-30, polybutene-31, polybutene-32, polybutene-33, polybutene-34, polybutene-35, polybutene-36, polybutene-37, polybutene-38, polybutene-39, polybutene-40, polybutene-41, polybutene-42, polybutene-43, polybutene-44, polybutene-45, polybutene-46, polybutene-47, polybutene-48, polybutene-49, polybutene-50, polybutene-51, polybutene-52, polybutene-53, polybutene-54, polybutene-55, polybutene-56, polybutene-57, polybutene-58, polybutene-59, polybutene-60, polybutene-61, polybutene-62, polybutene-63, polybutene-64, polybutene-65, polybutene-66, polybutene-67, polybutene-68, polybutene-69, polybutene-70, polybutene-71, polybutene-72, polybutene-73, polybutene-74, polybutene-75, polybutene-76, polybutene-77, polybutene-78, polybutene-79, polybutene-80, polybutene-81, polybutene-82, polybutene-83, polybutene-84, polybutene-85, polybutene-86, polybutene-87, polybutene-88, polybutene-89, polybutene-90, polybutene-91, polybutene-92, polybutene-93, polybutene-94, polybutene-95, polybutene-96, polybutene-97, polybutene-98, polybutene-99, polybutene-100.

Questions or comments?

1-800-LRP-LABO 1-800-517-5226
Monday-Friday 9a.m. - 5p.m. EST

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TINTED MINERAL LIGHT FLUID SUNSCREEN BROAD SPECTRUM SPF 40 DEEP

titanium dioxide and zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium dioxide (UNII: 15FIX9V2JP) (Titanium dioxide - UNII:15FIX9V2JP)	Titanium dioxide	170 mg in 1 mL
Zinc oxide (UNII: SOI2LOH54Z) (Zinc oxide - UNII:SOI2LOH54Z)	Zinc oxide	80 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ISOHEXADECANE (UNII: 918X1OUF1E)	
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIETHYLHEXANOIN (UNII: 7K3W1BIU6K)	
C15-19 ALKANE (UNII: C187N1IM01)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
TALC (UNII: 7SEV7J4R1U)	
DIMETHICONE/PEG-10/15 CROSSPOLYMER (UNII: 21AS8B1BSS)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW) (UNII: S7ZA3CCJ4M)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DISODIUM STEAROYL GLUTAMATE (UNII: 45ASM2L11M)	

PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
SENNA ALATA LEAF (UNII: 4BXR6YZN92)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-203-01	1 in 1 CARTON	12/15/2023	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-203-02	1 in 1 CARTON	12/15/2023	
2		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	12/15/2023	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(49967-203)

Establishment

Name	Address	ID/FEI	Business Operations
Interspray		364829903	pack(49967-203)

Revised: 12/2023

L'Oreal USA Products Inc