LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS TINTED MINERAL LIGHT FLUID SUNSCREEN BROAD SPECTRUM SPF 40 MEDIUM 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

dimethicone, isohexadecane, triethylhexanoin, c15-19 alkane, dicaprylyl carbonate, silica, iron oxides, c12-15 alkyl benzoate, caprylyl methicone, butyloctyl salicylate, aluminum stearate, 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, triethoxycaprylylsilane, disteardimonium hectorite, disodium stearoyl glutamate, 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)

LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS

TINTED MINERAL LIGHT FLUID SUNSCREEN BROAD SPECTRUM SPF 40 MEDIUM DEEP

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49967-943
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: CI87N1IM01)	
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)	
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: HIE492ZZ3T)	
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:49967-943-01	1 in 1 CARTON	12/15/2023	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:49967-943-02	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(49967-943)

Establishment

Name	Address	ID/FEI	Business Operations
Interspray		364829903	pack(49967-943)

Revised: 12/2023 L'Oreal USA Products Inc