

**LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS DERMO KIDS
GENTLE FACE AND BODY BROAD SPECTRUM SPF 60 SUNSCREEN WATER
RESISTANT 80 MINUTES- avobenzone, homosalate, octisalate and
octocrylene lotion
L'Oreal USA Products Inc**

Drug Facts

Active ingredient

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 7%

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:

- apply generously 15 minutes before sun exposure
- reapply:
 - after 80 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, C12-15 alkyl benzoate, propylene glycol, diisopropyl sebacate, styrene/acrylates copolymer, glycerin, alcohol denat., dimethicone, potassium cetyl phosphate, acrylates copolymer, ammonium polyacryloyldimethyl taurate, caprylic/capric triglyceride, caprylyl glycol, diethylhexyl syringylidenemalonate, disodium EDTA, glyceryl stearate, hydroxypropyl methylcellulose, isopropyl lauroyl sarcosinate, myristic acid, palmitic acid, PEG-100 stearate, PEG-8 laurate, pentylene glycol, phenoxyethanol, sodium chloride, stearic acid, t-butyl alcohol, tocopherol, triethanolamine

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



60
Face & Body

BROAD SPECTRUM
SPF 60

ANTHELIOS dermo-kids
gentle sunscreen lotion

with CELL-OX SHIELD® UVA/UVB PROTECTION

WITH LA ROCHE-POSAY
THERMAL SPRING WATER

WATER RESISTANT (80 MINUTES)
Suitable for sensitive skin
Pediatrician and Dermatologist tested
Fragrance-free, Paraben-free

6.7 FL.OZ. / 200 ml

INNOVATION

ANTHELIOS dermo-kids 60 provides broad-spectrum UVA/UVB protection with CELL-OX SHIELD® filtering system in a texture specifically developed to be gentle for children's skin. Applies easily, leaving skin feeling soft and smooth.

Properties:

1. Dermatological Safety:

A lightweight, comforting lotion without fragrance and parabens. Formulated to be gentle to skin and tested for skin tolerance.

2. UVA/UVB protection + antioxidants with POWERFUL CELL-OX SHIELD®

A combination of photostable UVA/UVB filters chosen for its synergistic effect to deliver broad-spectrum protection.

With antioxidants, including Vitamin E to help neutralize³ damaging free radicals.

³ upper layers of skin.

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Drug Facts (continued)

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693249 4 Code F.I.L.: D189662/1

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PARABEN-FREE
NON-COMEDOGENIC
ALLERGY TESTED
PEDIATRICIAN TESTED
DERMATOLOGIST TESTED
SUITABLE FOR SENSITIVE SKIN



2107796 - Made in USA
with US and/or Imported Ingredients.

Distribution reserved to
La Roche-Posay agreed distributors
Distributed by La Roche-Posay LLC,
10 Hudson Yards, New York, NY 10001
La Roche-Posay Laboratoire Pharmaceutique
36270 La Roche-Posay France
TSA 75000 93504 ST OUBIN CEDEX FR
www.laroche-posay.us



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 - children under 8 months of age: Ask a doctor

Drug Facts (continued)**Other information**

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

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La Roche-Posay Laboratoire Pharmaceutique
36270 La Roche-Posay, France
TSA 75000 36270 ST QUEN CEDEX FR
www.laroche-posay.us

LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS DERMO KIDS GENTLE FACE AND BODY BROAD SPECTRUM SPF 60 SUNSCREEN WATER RESISTANT 80 MINUTES

avobenzone, homosalate, octisalate and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-374
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	70 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ISOPROPYL LAUROYL SARCOSINATE (UNII: LYR06W430J)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
PALMITIC ACID (UNII: 2V16EO95H1)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TROLAMINE (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-374-01	200 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2016	
2	NDC:49967-374-02	300 mL in 1 TUBE; Type 0: Not a Combination Product	11/01/2016	
3	NDC:49967-374-03	3 mL in 1 PACKET; Type 0: Not a Combination Product	11/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M020	11/01/2016	
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Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
L'Oreal USA, Inc.		185931458	manufacture(49967-374) , pack(49967-374)

Revised: 12/2023

L'Oreal USA Products Inc