

LANCOME PARIS UV EXPERT AQUAGEL DEFENSE 50 PLUS SUNSCREEN BROAD SPECTRUM SPF 50 PLUS PRIMER AND MOISTURIZER WITH ANTIOXIDANT VITAMIN E- avobenzone, homosalate, octisalate and octocrylene cream
L'Oreal USA Products Inc

Drug Facts

Active ingredients

Avobenzone 3%

Homosalate 15%

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

Flammable until dry.

Do not use near fire, flame, or heat.

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 and evenly 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

Other information

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

Inactive ingredients

water, alcohol denat., styrene/acrylates copolymer, dimethicone, acrylates/dimethicone copolymer, tocopherol, dicaprylyl ether, sodium polyacrylate, sodium dodecylbenzenesulfonate, sodium benzoate, diethylhexyl syringylidenemalonate, phenoxyethanol, PEG-8 laurate, trisodium ethylenediamine disuccinate, menthyl lactate, pentylene glycol, mentha piperita (peppermint) extract, xanthan gum, propanediol, leontopodium alpinum flower/leaf extract, caprylyl glycol, caprylic/capric triglyceride, acrylates/c10-30 alkyl acrylate crosspolymer, moringa oleifera seed extract, rosa meichibon/delgramaue callus, disodium phosphate, butylene glycol, citric acid, potassium sorbate, glycerin, fragrance

Questions or comments?

1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)

<p>SUITABLE FOR SENSITIVE SKIN NON-COMEDOGENIC</p> <h3>Drug Facts (continued)</h3> <h4>Directions</h4> <p>For sunscreen use:</p> <ul style="list-style-type: none"> • apply generously and evenly 15 minutes before sun exposure • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating <p>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:</p> <ul style="list-style-type: none"> • 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 <h4>Other information</h4> <ul style="list-style-type: none"> • protect the product in this container from excessive heat and direct sun <h4>Inactive ingredients</h4> <p>water, alcohol denat., styrene/acrylates copolymer, dimethicone, acrylates/dimethicone copolymer, tocopherol, dicaprylyl ether, sodium polyacrylate, sodium dodecylbenzenesulfonate, sodium benzoate, diethylhexyl syringylenedimaleonate, phenoxetanol, PEG-8 laureate, trisodium ethylenediamine disuccinate, menthyl lactate, pentylene glycol, mentha piperita (peppermint) extract, xanthan gum, propenadiol, leontopodium alpinum flower/leaf extract, caprylyl glycol, caprylic/capric triglyceride, acrylates/C10-30 alkyl acrylate crosspolymer, moringa oleifera seed extract, rosa meichoni/delgamaea callus, disodium phosphate, butylene glycol, citric acid, potassium sorbate, glycerin, fragrance</p> <h4>Questions or comments?</h4> <p>1-800-LANCÔME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)</p>	 <h1>LANCÔME</h1> <p>PARIS</p> <h2>UV EXPERT</h2> <h3>AQUAGEL DEFENSE 50+</h3> <h4>SUNSCREEN</h4> <p>BROAD SPECTRUM SPF 50+ PRIMER & MOISTURIZER</p> <p>WITH ANTIOXIDANT VITAMIN E</p> <h4>AQUAGEL TECHNOLOGY</h4> <p>LIGHTWEIGHT + COOLING + INVISIBLE</p> <p>30 mL 1.0 FL.OZ.</p>	<h3>Drug Facts (continued)</h3> <p>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.</p>	<h3>Drug Facts (continued)</h3> <p>If used as directed with other sun protection products (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun. Warnings For external use only. Flammable until dry. Do not use near fire, flame or heat.</p> <table border="1"> <thead> <tr> <th>Active ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate 15%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 7%</td> <td>Sunscreen</td> </tr> </tbody> </table> <h4>Uses</h4> <ul style="list-style-type: none"> • helps prevent sunburn 	Active ingredients	Purpose	Avobenzone 3%	Sunscreen	Homosalate 15%	Sunscreen	Octisalate 5%	Sunscreen	Octocrylene 7%	Sunscreen
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C1 - Internal use

LANCÔME PARIS UV EXPERT AQUAGEL DEFENSE 50 PLUS

SUNSCREEN BROAD SPECTRUM SPF 50 PLUS PRIMER AND MOISTURIZER WITH ANTIOXIDANT VITAMIN E			
avobenzone, homosalate, octisalate and octocrylene cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-614
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	150 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
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)			
DIMETHICONE (UNII: 92RU3N3Y1O)			
2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW) (UNII: S7ZA3CCJ4M)			
TOCOPHEROL (UNII: R0ZB2556P8)			
DICAPRYLYL ETHER (UNII: 77JZM5516Z)			
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)			
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			
PEG-8 LAURATE (UNII: 762O8IWA10)			
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)			
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)			
PENTYLENE GLYCOL (UNII: 50C1307PZG)			
MENTHA X PIPERITA WHOLE (UNII: 79M2M2UDA9)			
XANTHAN GUM (UNII: TTV12P4NEE)			
PROPANEDIOL (UNII: 5965N8W85T)			
LEONTOPODIUM NIVALE SUBSP. ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)			
CAPRYLYL GLYCOL (UNII: 00YIU5438U)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)			
MORINGA OLEIFERA LEAF (UNII: 4WET1AWO9B)			
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)			
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
POTASSIUM SORBATE (UNII: 1VPU26JZ Z4)			

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-614-01	1 in 1 CARTON	12/22/2022	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-614-02	1 in 1 CARTON	12/22/2022	06/01/2026
2		10 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:49967-614-03	1 in 1 CARTON	12/22/2022	12/30/2024
3		5 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:49967-614-04	1 in 1 CARTON	12/22/2022	12/30/2024
4		1 mL in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:49967-614-05	1 in 1 CARTON	12/01/2023	
5		50 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	12/22/2022	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-614) , pack(49967-614)

Revised: 12/2023

L'Oreal USA Products Inc