

LANCOME UV EXPERT AQUAGEL DEFENSE 50 BROAD SPECTRUM SPF 50 WITH ANTIOXIDANT VITAMIN E- avobenzene, homosalate, octisalate, octocrylene and oxybenzone cream
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.

Drug Facts

Drug Facts

Avobenzene 3%

Homosalate 1.7%

Octisalate 3.2%

Octocrylene 6%

Oxybenzone 3.9%

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

- 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, dimethicone, alcohol denat., styrene/acrylates copolymer, acrylates/dimethicone copolymer, tocopherol, sodium polyacrylate, sodium dodecylbenzenesulfonate, sodium benzoate, phenoxyethanol, PEG-8 laurate, silica, pentylene glycol, mentha piperita (peppermint) extract, propylene glycol, leontopodium alpinum flower/leaf extract, caprylyl glycol, acrylates/C-10-30 alkyl acrylate crosspolymer, sorbitol, moringa oleifera seed extract, disodium EDTA, rosa gallica flower extract, disodium phosphate, citric acid, potassium sorbate, glycerin, fragrance

<p>SUITABLE FOR SENSITIVE SKIN NON-COMEDOGENIC</p> <p>Drug Facts (continued)</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 • 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: <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 <p>Other information</p> <ul style="list-style-type: none"> • protect the product in this container from excessive heat and direct sun <p>Inactive ingredients water, dimethicone, alcohol denat., styrene/acrylates copolymer, acrylates/dimethicone copolymer, tocopherol, sodium polyacrylate, sodium dodecylbenzenesulfonate, sodium benzoate, phenoxyethanol, PEG-8 laurate, silica, pentylene glycol, mentha piperita (peppermint) extract, propylene glycol, leontopodium alpinum flower/leaf extract, caprylyl glycol, acrylates/C10-30 alkyl acrylate crosspolymer, sorbitol, moringa oleifera seed extract, disodium EDTA, rosa gallica flower extract, disodium phosphate, citric acid, potassium sorbate, glycerin, fragrance</p> <p>Questions or comments? 1-800-LANCOME (1-800-526-2663) Monday - Friday (9 a.m. - 5 p.m. EST)</p> <p>C223182/1 889045</p> <p>LANCÔME PARIS Lancome.com LA402 10 30 ml</p>	<p>All Day Primer & Moisturizer UV EXPERT Aquagel Defense 50 Broad Spectrum SPF 50 All skin types, even sensitive</p> <p>This formula, enriched with Antioxidants Vitamin E, Edelweiss and Moringa, helps to protect the skin from external aggressions.</p> <p>Oil-free. All-day hydration.</p> <p>Apply this water-like refreshing, weightless and invisible formula every day on your face and neck, as a makeup primer or moisturizer.</p> <p>THIS PRODUCT CAN BE SOLD ONLY BY APPROVED DISTRIBUTORS LANCÔME PARIS 14 rue Royale 75008 Paris</p> <p>LANCÔME LUXURY PRODUCTS LLC 10 HUDSON YARDS NEW YORK, NY 10001 IMP. BY LANCÔME CANADA MONTREAL, H4T 1K5 TSA 75000 93584 ST. OVEN CEDEX FR</p> <p>Made in France</p>  <p>3 614272 489578</p> <p>Small Vector Code</p>	<p>LANCÔME PARIS</p> <p>UV EXPERT</p> <p>AQUAGEL DEFENSE 50 SUNSCREEN</p> <p>BROAD SPECTRUM SPF 50 ALL DAY PRIMER & MOISTURIZER</p> <p>WITH ANTIOXIDANT VITAMIN E</p> <p>AQUAGEL TECHNOLOGY OIL-FREE + COOLING + INVISIBLE</p> <p>30 ml 1.0 FL. OZ.</p>	<p>Drug Facts (continued)</p> <p>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> <p>Directions For sunscreen use.</p> <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • 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 <p>Warnings For external use only Do not use on damaged or broken skin</p> <p>Drug Facts</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 10.7%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 3.2%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 6%</td> <td>Sunscreen</td> </tr> <tr> <td>Oxybenzone 3.8%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses</p>	Active ingredients	Purpose	Avobenzone 3%	Sunscreen	Homosalate 10.7%	Sunscreen	Octisalate 3.2%	Sunscreen	Octocrylene 6%	Sunscreen	Oxybenzone 3.8%	Sunscreen
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49967-248
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	107 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	32 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	39 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
water (UNII: 059QF0K00R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALCOHOL (UNII: 3K9958V90M)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
SODIUM DODECYLBENZENESULFONATE (UNII: 554127163Y)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-8 LAURATE (UNII: 762O8IWA10)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
LEONTOPODIUM ALPINUM FLOWER (UNII: MWN6IZU3XM)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITOL (UNII: 506T60A25R)	
MORINGA OLEIFERA SEED OIL (UNII: REM6A5QMC0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ROSA GALLICA FLOWER (UNII: X8W61WUV70)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-248-01	1 in 1 CARTON	01/15/2018	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:49967-248-02	1 in 1 CARTON	01/15/2018	
2		10 mL in 1 TUBE; Type 0: Not a Combination Product		

3	NDC:49967-248-03	1 in 1 CARTON	01/15/2018	
3		5 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:49967-248-04	1 in 1 CARTON	01/15/2018	
4		1 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	01/15/2018	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment

Name	Address	ID/FEI	Business Operations
SICOS ET CIE		276993581	manufacture(49967-248)

Revised: 11/2018

L'Oreal USA Products Inc