

VICHY LABORATOIRES AQUALIA THERMAL SUNSCREEN- avobenzon e, homosalate, octisalate and octocrylene lotion
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

Active ingredients

Avobenzon e 3%

Homosalate 6%

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

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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

Directions

For sunscreen use:

- apply liberally 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, isononyl isononanoate, glycerin, dimethicone, diisopropyl sebacate, aluminum starch octenylsuccinate, sucrose tristearate, styrene/acrylates copolymer, polysorbate 61, PEG-12 dimethicone, PEG-8 laurate, carbomer, triethanolamine, dimethiconol, sodium stearyl glutamate, sodium hyaluronate, phenoxyethanol, tocopheryl acetate, disodium EDTA, caprylyl glycol, biosaccharide gum-1, xanthan gum, fragrance

Questions or comments?

Call toll free 1-877-378-4249

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

VICHY
LABORATOIRES



Sensitive skin
Allergy Tested
Vichy Thermal Spa Water

SUNSCREEN

**AQUALIA
THERMAL**

24 hr hydrating
fortifying lotion

Everyday UVA/UVB protection
Oil-free lightweight texture

BROAD SPECTRUM SPF 25

50 ml

1.69 FL.OZ

NORMAL SKIN



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INDICATIONS

Hydration and UVA/UVB protection for sensitive skin.
When skin becomes dehydrated, its protective barrier is weakened.
The skin is more vulnerable.

INNOVATION

For the 1st time at Vichy, an ultra-refreshing moisturizer associating Vichy Thermal Spa Water with broad spectrum protection against UVA and UVB rays.

UVA/UVB PROTECTION

Broad Spectrum SPF 25 Sunscreen

helps provide everyday protection from harmful UVA/UVB rays which may cause skin damage.

Vichy Thermal SPA Water: effectiveness clinically tested

A water exceptionally rich in rare minerals to fortify and soothe the skin:
- anti-oxidant properties to fight against free radicals caused by external aggressions.
- it helps strengthen the natural protective function of the skin and soothe sensations of discomfort, even on sensitive skin.

EFFICACY

Immediately, the skin is intensely hydrated, feels smoothed and refreshed. Skin feels smooth and free of sensation of tightness all day long. Hydration lasts all day for a 24hr continuous effect. The skin appears more resilient, with increased suppleness and radiance. With daily use, the skin gains extra-moisture.

PLEASURE

Oil-free refreshing lotion texture. The light, refreshing texture of Aqualia Thermal Lotion glides over the skin and penetrates instantly, without stickiness.

DERMATOLOGICALLY TESTED

Sensitive skin.
Allergy tested.

Distribution reserved to agreed Vichy suppliers

VICHY LLC, New York, NY 10017

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Call toll free 1-877-37-VICHY-(84249)
Monday - Friday (9 a.m. - 5 p.m. EST)

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Made in France www.vichyusa.com

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LABORATOIRES



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688482 12 - Code FLL : B48261/3.
US Pat. Pending

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avobenzone, homosalate, octisalate and octocrylene lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:49967-041

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	60 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)				
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)				
GLYCERIN (UNII: PDC6A3C0OX)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)				
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)				
SUCROSE TRISTEARATE (UNII: 71I93STU5M)				
POLYSORBATE 61 (UNII: X9E1MY2JQG)				
PEG-12 DIMETHICONE (UNII: ZEL54N6W95)				
PEG-8 LAURATE (UNII: 762O8IWA10)				
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)				
TROLAMINE (UNII: 9O3K93S3TK)				
DIMETHICONOL (100000 CST) (UNII: OSA9UP217S)				
HYALURONATE SODIUM (UNII: YSE9PPT4TH)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
CAPRYLYL GLYCOL (UNII: 00YIU5438U)				
BIOSACCHARIDE GUM-1 (UNII: BB4PU4V09H)				
XANTHAN GUM (UNII: TTV12P4NEE)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49967-041-01	1 in 1 CARTON	04/01/2013	
1		50 mL in 1 BOTTLE, PUMP; 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	04/01/2013	

Labeler - L'Oreal USA Products Inc (002136794)

Establishment			
Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(49967-041)