

**VICHY LABORATOIRES AQUALIA THERMAL UV DEFENSE MOISTURIZER BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate and octocrylene lotion**  
**L'Oreal USA Products Inc.**

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**Drug Facts**

**Active ingredients**

Avobenzone 3%

Homosalate 5%

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, glycerin, silica, dimethicone, niacinamide, PEG-100 stearate, glyceryl stearate, mannose, stearic acid, ceramide NP, dimethicone/vinyl dimethicone crosspolymer, sodium hydroxide, sodium PCA, myristic acid, palmitic acid, ammonium polyacryloyldimethyl taurate, tocopherol, capryloyl glycine, caprylyl glycol, trisodium ethylenediamine disuccinate, xanthan gum, cetyl alcohol, fragrance

## **Questions or comments?**

Call toll free 1-877-378-4249

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



By using a FSC® certified cardboard for this box, VICHY supports forest management that respects people and nature.

ALL SKIN TYPES

### Drug Facts

| Active ingredients | Purpose   |
|--------------------|-----------|
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| Homosalate 5%      | Sunscreen |
| Octisalate 5%      | Sunscreen |
| Ocotocrylene 7%    | Sunscreen |

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**Other information**

- protect the product in this container from excessive heat and direct sun
- store at 68-77°F (20-25°C)

**Inactive ingredients**

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### Drug Facts (continued)

taurate, tocopherol, caprylyl glycol, caprylyl glycol, triethylamine disuccinate, xanthan gum, cetyl alcohol, fragrance

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989007 03 B2279701

### VICHY STATEMENT

We formulate our products with pure VICHY MINERALIZING THERMAL WATER, born in the region of French Volcanoes. Rich in 15 minerals, it helps strengthen the skin's barrier to protect against daily aggressors. Our formulas are composed with NATURALLY INSPIRED and rigorously selected ingredients. TESTED ON SENSITIVE SKIN under dermatological control.



# VICHY

LABORATOIRES



Sensitive skin  
Allergy-tested  
Vichy Mineralizing Thermal Water

SUNSCREEN

## AQUALIA THERMAL

### UV DEFENSE MOISTURIZER BROAD SPECTRUM SPF 30

48-hr Dynamic Hydration  
Fortifies skin barrier  
Daily UVA/UVB protection  
Oil-free lightweight texture

50 ml 1.69 FL.OZ  
ALL SKIN TYPES • PARABEN FREE

**INNOVATION:** AQUALIA THERMAL UV DEFENSE MOISTURIZER SUNSCREEN is formulated with Niacinamide, Plant Sugar and Vichy Mineralizing Thermal Water. It also contains active sunscreen ingredients for broad spectrum SPF 30 protection.

**EFFICACY:** Immediately, skin is rehydrated. With reapplication at least every 2 hours, active sunscreen ingredients help protect against daily harmful UVA/UVB rays, which can cause skin damage and premature skin aging.

**AQUALIA THERMAL UV DEFENSE MOISTURIZER SUNSCREEN** provides 48hr dynamic hydration and smoothed fine lines. Skin appears less tired, leaving a healthy looking radiance.

**APPLICATION:** Apply morning on top of your daily serum or alone under makeup

**LIGHTWEIGHT TEXTURE:** This oil-free refreshing lightweight texture glides easily over skin without stickiness.

PARABEN-FREE  
NO OILS, COLORANTS  
SUITABLE FOR SENSITIVE SKIN  
ALLERGY-TESTED  
NON-COMEDOGENIC FORMULA  
DERMATOLOGIST TESTED FOR SAFETY



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Distribution reserved to agreed VICHY suppliers.  
Vichy LLC, New York, NY 10001  
www.vichyusa.com  
VICHY CA/CAF 03 Vichy France  
ISA 75000 93584 ST OZEN CEDEX FR  
Made in France www.vichy.com



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avobenzone, homosalate, octisalate and octocrylene lotion

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:49967-869 |
| <b>Route of Administration</b> | Topical        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE               | 30 mg in 1 mL   |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE               | 50 mg in 1 mL   |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE               | 50 mg in 1 mL   |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE              | 70 mg in 1 mL   |

**Inactive Ingredients**

| <b>Ingredient Name</b>   | <b>Strength</b> |
|--|-----------------|
| <b>WATER</b> (UNII: 059QF0KO0R)  |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)   |                 |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)  |                 |
| <b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)  |                 |
| <b>NIACINAMIDE</b> (UNII: 25X51I8RD4)  |                 |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)   |                 |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                                      |                 |
| <b>MANNOSE, D-</b> (UNII: PHA4727WTP)  |                 |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)   |                 |
| <b>CERAMIDE NP</b> (UNII: 4370DF050B)  |                 |
| <b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5) |                 |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)   |                 |
| <b>SODIUM PYRROLIDONE CARBOXYLATE</b> (UNII: 469OTG57A2)                             |                 |
| <b>MYRISTIC ACID</b> (UNII: 0I3V7S25AW)  |                 |
| <b>PALMITIC ACID</b> (UNII: 2V16EO95H1)  |                 |
| <b>AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S)</b> (UNII: F01RIY4371)        |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)   |                 |
| <b>CAPRYLOYL GLYCINE</b> (UNII: 8TY5YO42NJ)  |                 |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)  |                 |
| <b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)                      |                 |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |                 |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)  |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                            | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:49967-869-01 | 1 in 1 CARTON   | 05/27/2019                  |                           |
| 1        |                  | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product  |                             |                           |
| 2        | NDC:49967-869-02 | 1.5 mL in 1 PACKET; Type 0: Not a Combination Product | 05/27/2019                  |                           |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020                                     | 05/27/2019           |                    |

**Labeler** - L'Oreal USA Products Inc. (002136794)

## Establishment

| Name                         | Address | ID/FEI    | Business Operations                      |
|------------------------------|---------|-----------|--|
| Cosmetique Active Production |         | 282658798 | manufacture(49967-869) , pack(49967-869) |

## Establishment

| Name     | Address | ID/FEI    | Business Operations |
|----------|---------|-----------|---------------------|
| Socoplan |         | 276221405 | pack(49967-869)     |

Revised: 1/2024

L'Oreal USA Products Inc.