

**VICHY LABORATOIRES AQUALIA THERMAL UV DEFENSE BROAD SPECTRUM
SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate and
octocrylene lotion
Cosmetique Active Production**

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

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
Avobenzone 3%	Sunscreen
Homosalate 5%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 7%	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 sun

Warnings

For external use only

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- 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

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 - apply liberally 15 minutes before sun exposure
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 - 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
- store at 68-77°F (20-25°C)

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

Drug Facts (continued)

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

Questions or comments?

Call toll free 1-877-378-4248
Monday – Friday (9 a.m. to 8 p.m. EST)

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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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VICHY LABORATOIRES AQUALIA THERMAL UV DEFENSE BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69625-868
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	50 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: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MANNOSE, D- (UNII: PHA4727WTP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CERAMIDE NP (UNII: 4370DF050B)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
MYRISTIC ACID (UNII: 0I3V7S25AW)	
PALMITIC ACID (UNII: 2V16EO95H1)	
AMMONIUM POLYACRYLOYLDIMETHYL TAURATE (55000 MPA.S) (UNII: F01RIY4371)	
TOCOPHEROL (UNII: R0ZB2556P8)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69625-868-01	1 in 1 CARTON	05/27/2019	
1		50 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69625-868-02	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 final	M020	05/27/2019	

Labeler - Cosmetique Active Production (282658798)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmetique Active Production		282658798	manufacture(69625-868) , pack(69625-868)

Establishment

Name	Address	ID/FEI	Business Operations
Socoplan		276221405	pack(69625-868)

Revised: 1/2021

Cosmetique Active Production