

HERBAL ALOE FACE AND BODY SPF 30- avobenzene, homosalate, octisalate, octocrylene, oxybenzone cream

Herbalife International of America, 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.

Herbalife Herbal Aloe Face and Body Sunscreen SPF 30

Drug Facts

Purpose

Sunscreen

Active ingredients

Avobenzene (3%)

Homosalate (5%)

Octisalate (5%)

Octocrylene (2.7%)

Oxybenzone (5%)

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

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours
 - Children under 6 months: Ask a doctor
- **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

Other information

- Protect the product in this container from excessive heat and direct sunlight

Inactive ingredients: Water (Aqua), Polyamide-8, Isoamyl Laurate, Butylene Glycol, Glycerin, Isodecyl Neopentanoate, Glyceryl Stearate, Aloe Barbadensis Leaf Juice, PEG-100 Stearate, Tocopheryl Acetate, Helianthus Annuus (Sunflower) Seed Oil, Caprylic/ Capric Triglyceride, Yucca Filamentosa Extract, Artemisia Tridentata Extract, Simmondsia Chinensis (Jojoba) Seed Extract, Silybum Marianum Seed Extract, Salvia Hispanica Seed Extract, Agave Americana Leaf Extract, Physalis Angulata Extract, Polyacrylic Acid, Xylityl Sesquicaprylate, Euphorbia Cerifera (Candelilla) Wax, Diisopropyl Sebacate, Lauryl Lactate, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance (Parfum), Triethanolamine, Sodium Hydroxide, Disodium EDTA, Sodium Benzoate, Ethylhexylglycerin, Hexylene Glycol, Caprylyl Glycol, Phenoxyethanol.

Distributed by:

Herbalife International of America, Inc.

800 W. Olympic Blvd., Suite 406

Los Angeles, CA 90015, USA

Made in USA with US and imported ingredients.

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FOR EVERY BODY, EVERY DAY

PROTECTS SKIN FROM SUN'S

DAMAGING UVA/UVB RAYS

DOUBLES SKIN'S MOISTURE FOR 8 HOURS*

NO ADDED PARABENS • INCLUDES BOTANICALS

Protect your skin with this broad spectrum sunscreen that is sweat and water resistant up to 40 minutes. Contains aloe to hydrate skin, leaving it soft and smooth.

Pamper your skin and hair with our entire Herbal Aloe line:

- Strengthening Shampoo
- Strengthening Conditioner
- Hand & Body Wash
- Hand & Body Cream
- Soothing Aloe Gel
- Bath & Body Bar

The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen.

* Tested on subjects, measuring skin moisture levels at eight hour intervals. Skin of 86% of subjects showed double the moisture levels over baseline after eight hours.

HERBALIFE

HERBAL ALOE

FACE & BODY

SUNSCREEN

BROAD SPECTRUM SPF 30

SPF 30

SWEAT & WATER RESISTANT

(40 MINUTES)

4 fl oz (120 ml)



HERBAL ALOE

FACE & BODY SUNSCREEN BROAD SPECTRUM SPF 30

PROTECTOR SOLAR DE AMPLIO ESPECTRO FPS 30 PARA LA CARA Y EL CUERPO

SPF 30

SWEAT & WATER RESISTANT (40 MINUTES)
RESISTENTE AL AGUA Y AL SUDOR (40 MINUTOS)

4 fl oz | oz fl (120 ml)

HERBAL ALOE

FOR EVERY BODY, EVERY DAY PARA TODO TIPO DE PIEL, TODOS LOS DIAS

PROTECTS SKIN FROM SUN'S DAMAGING UVA/UVB RAYS
DOUBLES SKIN'S MOISTURE FOR 8 HOURS*
NO ADDED PARABENS • INCLUDES BOTANICALS

PROTEGE LA PIEL DE LOS DAÑOS QUE OCASIONAN LOS RAYOS UV/UVB
DUPLICA LA HIDRATACIÓN DE LA PIEL POR 8 HORAS*

SIN PARABENOS AÑADIDOS • INCLUYE INGREDIENTES BOTÁNICOS

Protect your skin with this broad spectrum sunscreen that is sweat and water resistant up to 40 minutes. Contains aloe to hydrate skin, leaving it soft and smooth.

Protege tu piel con este protector solar de alto espectro resistente al agua y al sudor por 40 minutos. Elaborado con sábila, la cual humecta la piel, dejándola suave y tersa.

Pamper your skin and hair with our entire Herbal Aloe line:

- Strengthening Shampoo
- Strengthening Conditioner
- Hand & Body Wash
- Hand & Body Cream
- Soothing Aloe Gel
- Bath & Body Bar

Mime a tu piel y cabello con la línea completa de Herbal Aloe:

- Shampoo Fortificante
- Acondicionador Fortificante
- Jabón Líquido Corporal
- Crema para las Manos y el Cuerpo
- Gel Suavizante
- Barra de Jabón Corporal

The Skin Cancer Foundation recommends this product as an effective broad spectrum sunscreen.

La fundación de prevención contra el cáncer de piel, Skin Cancer Foundation, recomienda este producto por su filtro solar con protección de amplio espectro.

* Tested on subjects, measuring skin moisture levels at eight hour intervals. Skin of 86% of subjects showed double the moisture levels over baseline after eight hours.

* Probado en sujetos, midiendo los niveles de hidratación de la piel en intervalos de ocho horas. El 86% de los sujetos mostró el doble de hidratación en la piel sobre el nivel base por más de ocho horas.

Drug Facts

Active Ingredients	Purpose
Avobenzone (3%)	Sunscreen
Homosalate (5%)	
Octisalate (5%)	
Octocrylene (2.7%)	
Oxybenzone (5%)	

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Información del medicamento

Ingredientes activos	Propósito
Avobenzone (3%)	Protector Solar
Homosalate (5%)	
Octisalate (5%)	
Octocrylene (2.7%)	
Oxybenzone (5%)	

Usos

- Ayuda a prevenir las quemaduras del sol
- Si se usa según las instrucciones, junto con otras medidas de protección solar (ver **Instrucciones**), reduce el riesgo de cáncer de piel y el envejecimiento prematuro de la piel causado por la exposición solar

Advertencias

Para uso externo únicamente

No lo uses sobre la piel lastimada o quemada

Interrumpe su uso y consulta a un médico en caso de irritar la piel

Al usar este producto, evita el contacto con los ojos. Enjuaga con bastante agua para removerlo.

Mantener fuera del alcance de los niños. En caso de ingestión, obtén ayuda médica o comunícale inmediatamente con el Centro de Toxicología y Envenenamiento.

Instrucciones

- Aplica este producto generosamente 15 minutos antes de la exposición al sol
- Volver a aplicar:
 - Después de nadar o sudar por 40 minutos
 - Inmediatamente después de secarse con una toalla
 - Por lo menos cada dos horas
- Niños menores de seis meses de edad: consulta a un médico
- **Medidas de Protección al Exponerse al Sol.** Pasar tiempo bajo el sol aumenta el riesgo de contraer cáncer de piel y envejecimiento prematuro de la piel. Disminuye este riesgo usando un filtro solar de FPS 15 o mayor con frecuencia, y sigue otras medidas de protección como las siguientes:
 - Limita el tiempo de exposición al sol, especialmente entre las horas de las 10 de la mañana a las 2 de la tarde
 - Viste camisa de mangas largas, pantalones, sombrero y gafas de sol

Otra información

- Protege el producto en este envase del calor excesivo y rayos de sol directos

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Herbalife International of America, Inc.
800 W. Olympic Blvd., Suite 406
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Made in USA with US and imported ingredients.
Hecho en EUA con ingredientes estadounidenses e importados.

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HERBAL ALOE FACE AND BODY SPF 30

avobenzone, homosalate, octisalate, octocrylene, oxybenzone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51785-921
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	7.2 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	6.24 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	6.06 g in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.8844 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.4 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
YUCCA FILAMENTOSA (UNII: T6VR38UJ9I)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
CHIA SEED (UNII: NU0OLX06F8)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ARTEMISIA TRIDENTATA TOP OIL (UNII: 84183U1G10)	
NEOPENTYL GLYCOL (UNII: QI80HXD6S5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYAMIDE-8 (4500 MW) (UNII: 77723GV81A)	
AGAVE AMERICANA LEAF (UNII: 8511ZMP5QK)	
PHYSALIS ANGULATA (UNII: W4TKW9D5GG)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
TROLAMINE (UNII: 9O3K93S3TK)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
LAURYL LACTATE (UNII: G5SU0BFK7O)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
CANDELILLA WAX (UNII: WL0328HX19)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
WATER (UNII: 059QF0K00R)	
MILK THISTLE (UNII: U946SH95EE)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
DIISOPROPYL SEBACATE (UNII: J8T3X564IH)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51785-921-02	1 in 1 CARTON	08/25/2014	
1		120 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 final	part352	08/25/2014	

