

## **HAWAIIAN SPF 30 ALOE SUNSCREEN- avobenzene, homosalate, octocrylene, octisalate lotion**

**The Hain Celestial Group, 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.*

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### **Hawaiian SPF 30 Aloe Sunscreen Lotion**

Avobenzene 3%

Homosalate 10%

Octocrylene 10%

Octisalate 5%

● Apply liberally 15 minutes before sun exposure ● Reapply: ● after 80 minutes of swimming or sweating ● immediately after towel drying ● at least every 2 hours ● Children under 6 months of age: 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 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 am - 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses

Sunscreen

For external use only. Do not use on broken or damaged skin. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if skin rash occurs. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Water (Aqua), Butyloctyl Salicylate, Dodecane, VP/Hexadecene Copolymer, Polyglyceryl-10 Pentastearate, Glycerin, Cetyl Alcohol, Glyceryl Stearate SE, Glyceryl Oleate Citrate, Behenyl Alcohol, Phenoxyethanol, Aloe Barbadosensis Leaf Juice (1), Calendula Officinalis Flower Extract (1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Ginkgo Biloba Leaf Extract (1), Lavandula Angustifolia (Lavender) Flower/Leaf/ Stem Extract (1), Panax Ginseng Root Extract (1), Tocopheryl Acetate, Caprylic/Capric Triglyceride, Cetearyl Oliviate, Citric Acid, Decane, Nonane, Potassium Hydroxide, Sodium Phytate, Sodium Stearoyl Lactylate, Solanum Tuberosum (Potato) Starch, Sorbitan Oliviate, Alcohol (1), Ethylhexylglycerin, Potassium Sorbate, Sodium Benzoate

(1) Certified Organic Ingredient

- 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

biodegradable & cruelty free

botanically moisturizing sunscreen

**alba**  
BOTANICA  
hawaiian

broad spectrum spf  
**30**

aloe vera  
sunscreen lotion

water resistant (80 minutes)  
free of oxybenzone & octinoxate

3 fl. oz. (89 ml)

RECOMMENDED  
SKIN CANCER  
ACTIVE

**Drug Facts**

Active ingredients	Purpose
Avobenzone 3% w/w	Sunscreen
Homosalate 10% w/w	Sunscreen
Octocrylene 10% w/w	Sunscreen
Octisalate 5% w/w	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 skin rash occurs.  
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 80 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 risk, regularly use a sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including:  
• Limit time in sun, especially from 10 a.m. - 2 p.m. • and wear long-sleeved shirts, pants, hats and sunglasses.

**Inactive ingredients**  
Water, Alcohol, Butylchitosan, Silica, Dicapryl Diglycol, VPHexadecane Copolymer, Polydecyl-10-Pentacosanoate, Glycerin, Cetyl Alcohol, Glycerol Stearate SE, Glyceryl Oleate Citrate, Behenyl Alcohol, Phenoxethanol, Aloe Barbadensis Leaf Juice<sup>1</sup>, Calendula Officinalis Flower Extract<sup>1</sup>, Camellia Sinensis Leaf Extract<sup>1</sup>, Chamomilla Recutita (Matricaria) Flower Extract<sup>1</sup>, Ginkgo Biloba Leaf Extract, Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract<sup>1</sup>, Panax Ginseng Root Extract, Tocopherol Acetate, Caprylyl Glycol, Triethyl Citrate, Citric Acid, Decane, Nonane, Potassium Hydroxide, Sodium Phosphate, Sodium Stearyl Lactate, Salicornia tuberosum (Petalot) Starch, Sorbitan Oleate Alcohol<sup>1</sup>, Ethylhexylglycerin, Potassium Sorbate, Sodium Benzoate.  
<sup>1</sup>Certified Organic Ingredient.

**Other information**  
Protect this product from excessive heat and direct sun. Store in room temperature 59°F-86°F.

**Questions?** Call (888) 658-7739 or visit [www.albabotanicals.com](http://www.albabotanicals.com)

biodegradable formula

**NO**  
oxybenzone, octinoxate,  
animal testing, synthetic fragrances,  
artificial colors, parabens, phthalates,  
sulfates or petrolatum  
100% vegetarian ingredients

MANUFACTURED BY:  
The Hain Celestial Group, Inc.  
Lake Success, NY 11042 USA  
©2022 Alba Botanica Products, Inc.  
Made in USA with ethically sourced materials.  
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## HAWAIIAN SPF 30 ALOE SUNSCREEN

avobenzone, homosalate, octocrylene, octisalate lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61995-2028
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
GINKGO BILOBA WHOLE (UNII: 660486U6OI)	
PANAX GINSENG ROOT OIL (UNII: P9T4K47OM0)	
CALENDULA OFFICINALIS WHOLE (UNII: PFR03EBU0H)	
MATRICARIA CHAMOMILLA WHOLE (UNII: G0R4UBI2ZZ)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)	
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)	
ALCOHOL (UNII: 3K9958V90M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
STARCH, POTATO (UNII: 8I089SAH3T)	
C9-11 ALKANE/CYCLOALKANE (UNII: 3EZ541F5MW)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2028-1	59 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	
2	NDC:61995-2028-2	89 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	
3	NDC:61995-2028-3	113 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/19/2019	

**Labeler** - The Hain Celestial Group, Inc (117115556)

**Registrant** - The Hain Celestial Group, Inc (014334364)

## Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc		081512382	manufacture(61995-2028)

Revised: 2/2023

The Hain Celestial Group, Inc