

ALBA BOTANICA HW SUNSCREEN GREEN TEA SPF45- avobenzone,homosalate, octocrylene,octyl salicylate 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.

Alba Botanica Hawaiian Green Tea SPF 45 Lotion

Active Ingredient

Avobenzone - 3.0%

Homosalate - 10.0%

Octocrylene - 10.0%

Ethylhexyl Salicylate - 5.0%

Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours.

Sunscreen

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 Poison Center right away.

Water, Glycerin, Glyceryl Stearate SE, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, VP/Hexadecene Copolymer, Caprylic/Capric Triglyceride, , Aloe Barbadensis Leaf Juice(1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Calendula Officinalis Flower Extract (1),Citrus Aurantium Dulcis ((Orange) Peel Oil, Lavandula Angustifolia (Lavender) Extract (1), Ginkgo Biloba Leaf Extract, Cetearyl Alcohol, Cetearyl Oliviate, Citric Acid, Polysorbate 60, Sodium Chloride, Sodium Stearoyl Glutamate, Sorbitan Oliviate, Tocopheryl Acetate, Triethyl Citrate, Xanthan Gum, Alcohol (1), Benzyl Alcohol, Potassium Sorbate, Sodium Benzoate.

(1) Certified Organic Ingredient

Helps prevent sunburns. If used as directed with other sun protection measures, decreases risk of skin cancer and early skin aging caused by sun exposure. Skin Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including: limit time in sun, especially from 10am to 2pm, and wear long sleeved shirts, pants, hats and sunglasses.



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avobenzone,homosalate, octocrylene,octyl salicylate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 1995-2011
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Route of Administration

TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GINKGO (UNII: 19FUJ2C58T)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ORANGE OIL (UNII: AKN3KSD11B)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2011-4	113 g in 1 TUBE; Type 0: Not a Combination Product	12/26/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/26/2016	

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.		014334364	manufacture(61995-2011)

Revised: 9/2019

The Hain Celestial Group, Inc.