

AL0083103 ALBA HAWAIIAN DRY COCONUT SUNSCREEN SPF15- octisalate, octocrylene, avobenzone oil

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 Coconut Dry Oil Sunscreen SPF 15

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.

Avobenzone - 2.0%

Octyl Salicylate - 5.0%

Octocrylene - 7.5%

Purpose: Sunscreen

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

Carthamus Tinctorius (Safflower) Seed Oil (1), Ethylhexyl Palmitate, Cocos Nucifera (Coconut) Oil (1), Butyrospermum Parkii (Shea) Butter, Citrus Aurantium Dulcis (Orange) Peel Oil, Daucus Carota Sativa (Carrot) Seed Oil, Juniperus Virginiana Oil, Macadamia Ternifolia Seed Oil, Tocopherol, Tocopheryl Acetate, Phenoxyethanol, Caprylic/Capric Triglyceride, Allyl Caproate, Ethyl Acetate.

(1) Certified Organic Ingredient

Apply liberally before Sun exposure. Reapply after 40 minutes of swimming or sweating, immediately after towel drying and 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 sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including: limit time in the sun, especially from 10am to 2pm, and wear long-sleeved shirts, pants, hats and sunglasses.

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Escape to paradise with this tropically tantalizing and botanically moisturizing dry oil with sunburn protection.

Drug Facts	Purpose
Active Ingredient	
Avobenzone 2.0%	Sunscreen
Octocrylene 7.5%	Sunscreen
Octyl Salicylate 5.0%	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 40 minutes of swimming or sweating, immediately after towel drying and 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 the sun, especially from 10am to 2pm, • and wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients: Carthamus Tinctorius (Safflower) Seed Oil, Ethylhexyl Palmitate, Cocos Nucifera (Coconut) Oil, Butyrospermum Parkii (Shea) Butter Oil, Citrus Aurantium Dulcis (Orange) Peel Oil, Cassia Cinnamomea (Cassia) Seed Oil, Juniperus Virginiana Oil, Mecardonia Ternstroemia Seed Oil, Tocopherol, Tocopherol Acetate, Nyl Caproate, Cetyl/Cearyl Trihydroxystearate, Ethyl Acrylate, Gamma-Decalactone, Gamma-Nonalactone, Gamma-Undecalactone, Isomyl Acrylate, Methyl Citrate, Vanillin, Phenoxethanol, Garamitol, Limonene, Linalool. ¹Certified Organic Ingredient

Other Information
Protect this product from excessive heat and direct sun.

Questions? Call (800) 659-7730 or visit www.albabotanica.com

free of sunscreen active ingredients that may harm coral reefs.
100% vegetarian ingredients.
not:
gluten, animal testing,
artificial colors, synthetic
fragrances, parabens,
phthalates or harmful sulfates

MANUFACTURED BY:
The Hain Celestial Group, Inc.
Lake Success, NY 11042 USA
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LAB00831WA008

133 ml e 4.5 fl oz

7 24742 100331 4

4.2500

@ 15% PMS 7549

PRESS DIRECTION

AL0083103 ALBA HAWAIIAN DRY COCONUT SUNSCREEN SPF15

octisalate, octocrylene, avobenzone oil

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:61995-2083

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 133 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7.5 g in 133 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 133 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARROT SEED OIL (UNII: 595AO13F11)	
MACADAMIA OIL (UNII: 515610SU8C)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HE492ZZ3T)	
ORANGE OIL (UNII: AKN3KSD11B)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2083-4	133 g in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/14/2017	

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(61995-2083)