

ALBA HAWAIIANDRY SUNSCREEN SPF15- homosalate, 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.

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.

Drug Facts

Homosalate 10%

Ethylhexyl Salicylate 5.0%

Octocrylene 3.0%

Butyl Methoxydibenzoylmethane 2.0%

Purpose: Sunscreen

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

Sun Protection Measures: Spending time

Ethylhexyl Palmitate, Carthamus Tinctorius (Safflower) Seed Oil (1), Cocos Nucifera (Coconut) Oil (1), Butyrospermum Parkii (Shea) Butter, Daucus Carota Sativa (Carrot) Seed Oil, Tocopherol, Tocopherol Acetate, Phenixyethanol, Fragrance.

(1) Certified Organic Ingredient

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

alba
BOTANICA®

**hawaiian
dry-oil
sunscreen**

nourishing
coconut oil
spf15
broad spectrum
water resistant (40 minutes)
biodegradable · gluten free

no parabens, phthalates
or animal testing
100% vegetarian ingredients

133 ml e 4.5 fl oz

Drug Facts

Active Ingredient	Purpose
Homosalate 10.0 %	Sunscreen
Ethylhexyl Salicylate 5.0 %	Sunscreen
Octocrylene 3.0 %	Sunscreen
Butyl Methoxydibenzoylmethane 2.0 %	Sunscreen

Uses • Helps prevent sunburn • If used as directed with other sun protection measure (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 Ethylhexyl Palmitate, Cetearyl Triethoxysilane, Stearic Acid, Cocos Nucifera (Coconut) Oil, Butyrospermum Parvi (Shea) Butter, Cocos Nucifera (Coconut) Seed Oil, Macadamia Ternstroemia Seed Oil, Tocopherol, Tocopherol Acetate, Phenoxyethanol, Benzyl Alcohol, Benzyl Benzoate, Coumarin, Limonene, Linalool, Fragrance (Parfums) *Certified Organic Ingredient

Other Information
Protect this product from excessive heat and direct sun

Questions? Call (800) 658-7730 or visit www.albabotanica.com

100% Vegetarian Ingredients.

No:
Animal Testing,
Artificial Colors,
Parabens,
Phthalates,
Sodium Lauryl/Laureth Sulfate
or Sodium Myreth Sulfate.

MANUFACTURED BY:
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LAB0081W4003



  



ALBA HAWAIIANDRY SUNSCREEN SPF15

homosalate, octisalate, octocrylene, avobenzene oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10.0 g in 133 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 133 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3.0 g in 133 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2.0 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: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2102-4	133 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/14/2014	

Labeler - The Hain Celestial Group, Inc. (858894996)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture(61995-2102)