

ALBA BODY DAILY SHADE SPF15- homosalate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane 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.

Active Ingredient

Homosalate 7.5%

Ethylhexyl Salicylate 5.0%

Octocrylene 3.0%

Butyl Methoxydibenzoylmethane 2.0%

For sunscreen use apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Use water resistant sunscreen when swimming or sweating.

Sunscreen

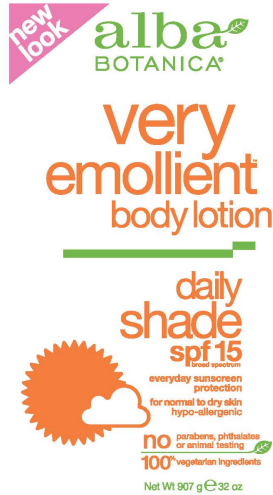
For external use only. Do not use on damaged or broken skin. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if skin rash occurs.

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

Water, Glycerin, Glyceryl Stearate SE, Carthamus Tinctorius (Safflower) Seed Oil, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, Hydrogenated Palm Cernel Oil, Persea Gratissima (Avocado) Oil, Sesamum Indicum (Sesame) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Oil (1), Vitis Vinifera (Grape) Seed Oil, Aloe Barbadensis Leaf Juice (1), Camellia Sinensis, Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Cucumis Sativus (Cucumber) Fruit Extract, Lavandula Angustifolia (Lavender) Extract, Echinacea Purpurea Extract, Allantoin, Ascorbic Acid, Butyrospermum Parkii (Shea) Butter, Lactic Acid, Glycolic Acid, Lecithin, Panthenol, Polysorbate 60, Tocopheryl Acetat, Xanthan Gum, Alcohol (1), Benzoic Acid, Dehydroacetic Acid, Benzyl Alcohol, Phenoxyethanol.

(1) Certified Organicf Ingredient

Helps prevents sunburns. If uses 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.



Your skin's secret to self defense
 Don't be intimidated by the words daily shade on your skin. This lightweight lotion, packed with botanical emollients, provides daily broad spectrum sunscreen protection and mega moisturization to your skin space naturally soft. A trio of apricot, green tea and chamomile extracts, plus a hefty punch of antioxidants and alpha hydroxy acids, moisturize and regenerate skin on contact while encouraging skin rejuvenation. Richly hydrating and hypo-allergenic, this invisible body cream soothes so subtly you'd forget it's there. Being it on.

Drug Facts	
Active Ingredient	Purpose
Homosalate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 3.0%	Sunscreen
Butyl Methoxydibenzoylmethane 2.7%	Sunscreen
Uses - Use as directed. Use this product with other sun protection measures (see Directions) whenever you are in the sun or near UV light sources. Use as directed.	
Warnings - For external use only. Do not use on damaged or irritated skin. When using this product, keep your skin cool. Avoid sunbathing. Do not use if you have a history of skin cancer. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (202) 638-2424.	
Directions - For sunscreen use, apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Use Protection Maximum: Sunburn Free in Up to 80% of Sun Exposure and Up to 90% of Sun Exposure. Do not use if you have a history of skin cancer. Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center (202) 638-2424.	
Other Information - Protect the product from excessive heat and direct sun.	

100% Vegetarian Ingredients.
 No Animal Testing, Artificial Colors, Parabens, Phthalates, Sodium Lauryl Sulfate or Sodium Myristate.
 Manufactured By: 40014 The Herb Cosmetics Group, Inc. Lake Success, NY 11042
 Product of U.S.A.
 Customer's Call (800) 969-7700 or visit www.AlbaBotanica.com



ALBA BODY DAILY SHADE SPF15

homosalate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2037
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	3 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LACTIC ACID (UNII: 33X04XA5AT)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY8IZ83H0X)	

GLYCERIN (UNII: PDC6A3C0OX)
WATER (UNII: 059QF0K00R)
SHEA BUTTER (UNII: K49155WL9Y)
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
SAFFLOWER OIL (UNII: 65UEH262IS)
CETYL ALCOHOL (UNII: 936JST6JCN)
DIMETHICONE (UNII: 92RU3N3Y1O)
ALLANTOIN (UNII: 344S277G0Z)
BENZOIC ACID (UNII: 8SKN0B0MIM)
DEHYDROACETIC ACID (UNII: 2KAG279R6R)
AVOCADO OIL (UNII: 6VNO72PFC1)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CHAMOMILE (UNII: FGL3685T2X)
CUCUMBER (UNII: YY7C30VXJT)
XANTHAN GUM (UNII: TTV12P4NEE)
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)
GRAPE SEED OIL (UNII: 930MLC8XGG)
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)
GLYCOLIC ACID (UNII: 0WT12SX38S)
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)
SESAME OIL (UNII: QX10HYY4QV)
JOJOBA OIL (UNII: 724GKU717M)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
PANTHENOL (UNII: WV9CM0O67Z)
POLYSORBATE 60 (UNII: CAL22UVI4M)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2037-9	907 g in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/11/2013	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture(61995-2037)

