

AL0043700 ALBA BOTANICA BABY MINERAL SUNSCREEN SPF50- zinc oxide 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 Baby Mineral Sunscreen SPF 50

Active Ingredient

Zinc Oxide - 17.0%

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. Children under 6 months: ask a doctor.

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, Caprylic Capric Triglyceride, Coconut Alkanes, Mica, Glycerin, Polyglyceryl-2 Sesquioleate, Polyglyceryl-3 Ricinoleate, Glyceryl Isostearate, Aloe Barbadensis Leaf Juice(1), Butyrospermum Parkii (Shea) Butter, Citrus Aurantium Dulcis (Orange) Peel Oil, Copernicia Cerifera (Carnauba) Wax, Juniperus Virginiana Oil, Camilla Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Brassica Alcohol, Coco-Caprylate/Caprates, Sodium Chloride, Alcohol (1), Polyhydroxystearic Acid, Tocopheryl Acetate, Biosaccharide Gum-1, C10-18 Triglycerides, Cetearyl Olivinate, Glyceryl Caprylate, Potassium Hydroxide, Quartz, Sodium Anisate, Sorbitan Olivinate, Ethylhexylglycerin.

(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.

4 ± 1.5

B



alba BOTANICA™

new



baby mineral sunscreen

spf 50+ broad spectrum

hypo-allergenic • pediatrician tested water resistant (80 minutes) reef safe • biodegradable

no oxybenzone, octinoxate or synthetic fragrances 100% vegetarian ingredients

Net Wt 113 g e 4 oz

seriously gentle protection for baby's delicate skin

Drug Facts

Active Ingredient Purpose Zinc Oxide 17.0 % 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 80 minutes of swimming or sweating. Immediately after towel drying and at least every 2 hours. Children under 2 months, ask a doctor. Sun Protection Measures: Spending time in the sun increase 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 10am to 2pm, and wear long-sleeved shirts, pants, hats and sunglasses.

Free of sunscreen active ingredients that may harm coral reefs.

100% Vegetarian Ingredients

No: gluten, animal testing, artificial colors, synthetic fragrances, parabens, phthalates or harmful sulfates

MANUFACTURED BY: The Hain Celestial Group, Inc. Lisle, Success, NY 11042 USA ©2017 Avon/Natural Products, Inc. TUB00457AL003

Inactive Ingredients

Alta Bulbosissima Leaf Juice*, Caprylic/Capric Triglyceride, Aqua (Water), Coconut Alkanes, Niacin, Glycerin, Polyglyceryl-2 Sebacate, Brassica Alcohol, Polyglyceryl-3 Ricinoleate, Glyceryl laurates, Butyrospermum Perseu (Shea) Butter, Citrus Aurantium Dulcis (Orange) Peel Oil, Juniperus Virginiana Oil, Camellia Sinensis Leaf Extract*, Chamomilla Recutita (Matricaria) Flower Extract*, Tocopheryl Acetate, Alcohol*, Anisole, Benzof Acetate, Benzocaine, Benzyl Alcohol, C10-18 Triglycerides, Cetylal Olivels, Coco-Caprylate/Caprate, Copernicia Cerifera (Carnauba) Wax, Cetylal Caprylate, Polyhydroxybutyrate, Potassium Hydroxide, Quartz, Sodium Arsenite, Sodium Chloride, Sodium Levulinate, Sodium Olivels, Triethyl Citrate, Vanillin, Ethylhexylglycerin, Phenoxyethanol, Citronellol, Geranyl, Limonene, Linalool *Certified Organic Ingredient

Other Information

Protect this product from excessive heat and direct sun

Questions?

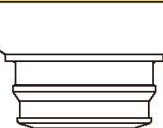
Call 888-655-7730 or visit www.albabotanica.com



2 ± 0.5mm

1

103 ± 1MM



AL0043700 ALBA BOTANICA BABY MINERAL SUNSCREEN SPF50

zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2437
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	17 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MICA (UNII: V8A1AW0880)	
BIO SACCCHARIDE GUM-1 (UNII: BB4PU4V09H)	
ORANGE OIL (UNII: AKN3KSD11B)	
POLYGLYCERYL-2 SESQUISO STEARATE (UNII: LA272Q68GQ)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
ALCOHOL (UNII: 3K9958V90M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
WATER (UNII: 059QF0KO0R)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CHAMOMILE (UNII: FGL3685T2X)	
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2437-4	113 g in 1 TUBE; Type 0: Not a Combination Product	12/21/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/21/2017	

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.		08 1512382	manufacture(61995-2437)

Revised: 2/2021

The Hain Celestial Group, Inc.