

ALBA BOTANICA BABY MINERAL SUNSCREEN SPF45- zinc oxide, titanium dioxide cream

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 SPF45 AL01017

Active Ingredient

Zinc Oxide 9.0%

Titanium Dioxide 7.0%

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 rash occurs.

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

Water, Caprylic Capric Triglyceride, Isoamyl Laurate, Coconut Alkanes, Polyglyceryl-2 Sesquioleate, Glycerin, Polyglyceryl-3 Ricinoleate, Aloe Barbadensis Leaf Juice(1), Crambe Abyssinica Seed Oil, Polyhydroxystearic Acid, Alumina, Stearic Acid, Butyrospermum Parkii (Shea) Butter, Camilla Sinensis Leaf Extract (1), Echinacea Purpurea Extract, Ginkgo Biloba Leaf Extract (1), Polygonum Aviculare Extract, Tocopheryl Acetate, Citric Acid, Coco-Caprylate/Caprinate, Magnesium Sulfate, Sodium Chloride, Sorbitan Sesquioleate, Alcohol (1), Benzyl Alcohol, Phenoxyethanol, 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.

seriously gentle and clear protection for baby's delicate skin

Drug Facts

Active Ingredient	Purpose
Titanium Dioxide 7.0 %	Sunscreen
Zinc Oxide 9.0 %	Sunscreen

Uses • Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases 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. • 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 sun, especially from 10am to 2pm. • wear long-sleeved shirts, pants, hats and sunglasses. • Children under 6 months: ask a doctor.

Inactive Ingredients Water (Aqua), Caprylic/Capric Triglyceride, Isoamyl Laurate, Coconut Alkanes, Polyglyceryl-2 Sesquiolate, Glycerin, Polyglyceryl-3 Ricinoleate, Aloe Barbadensis Leaf Juice⁽¹⁾, Crambe Abyssinica Seed Oil, Polyhydroxystearic Acid, Alumina, Stearic Acid, Butyrospermum Parkii (Shea) Butter, Camellia Sinensis Leaf Extract⁽¹⁾, Echinacea Purpurea Extract, Ginkgo Biloba Leaf Extract⁽¹⁾, Polygonum Aviculare Extract, Tocopheryl Acetate, Citric Acid, Coco-Caprylate/Caprate, Magnesium Sulfate, Sodium Chloride, Sorbitan Sesquiolate, Alcohol⁽¹⁾, Benzyl Alcohol, Phenoxethanol, Potassium Sorbate, Sodium Benzoate.
⁽¹⁾Certified Organic Ingredient

Other Information

Protect this product from excessive heat and direct sun

Questions?

Call (888) 659-7730 or visit www.albabotanica.com

*free of ingredients identified to have potential adverse impact to coral reefs

NO

oxybenzone, octinoxate, animal testing, synthetic fragrances, artificial colors, parabens, phthalates or sulfates

100% vegetarian ingredients

MANUFACTURED BY:
 The Hain Celestial Group, Inc.,
 Lake Success, NY 11042 USA
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 TUB01017AL001



new look

Reef friendly & cruelty free

alba BOTANICA

baby clear mineral sunscreen broad spectrum spf 45



45 hypo-allergenic pediatrician tested water resistant (80 minutes) biodegradable formula

NET WT 3oz (85g)

ALBA BOTANICA BABY MINERAL SUNSCREEN SPF45

zinc oxide, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
POLYGLYCERYL-2 SESQUIOLEATE (UNII: RHP7Q83BVB)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
CRAMBE HISPANICA SUBSP. ABYSSINICA SEED OIL (UNII: 0QW9S92J3K)	
WATER (UNII: 059QF0KO0R)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
SHEA BUTTER (UNII: K49155WL9Y)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GINKGO (UNII: 19FUJ2C58T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2017-1	85 g in 1 TUBE; Type 0: Not a Combination Product	12/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/19/2019	

Labeler - The Hain Celestial Group, Inc. (117115556)

Registrant - The Hain Celestial Group, Inc. (081512382)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		081512382	manufacture(61995-2017)

Revised: 4/2021

The Hain Celestial Group, Inc.