

ALBA MINERAL SUNSCREEN SPORT SPF45 BROAD SPECTRUM- 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.

Active Ingredient

Zinc Oxide 9.0 %

Titanium Dioxide 7.0 %

Cream. 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.

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.

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, Crambe Abyssinica Seed Oil, Aloe Barbadensis Leaf Juice(1), Polyhydroxystearic Acid, Echinacea Purpurea Extract, Polygonum Aviculare Extract, Tocopheryl Acetate, Butyrospermum Parkii (Shea) Butter, Camilla Sinensis Leaf Extract (1), Ginkgo Biloba Leaf Extract (1), Brassica Campestris (Rapeseed) Seed Oil, Alumina, Coco-Caprylate/Caprates, Magnesium Sulfate, Sodium Chloride, Sorbitan Sesquioleate, Stearic Acid, 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.

ALBA MINERAL SUNSCREEN SPORT SPF45 BROAD SPECTRUM			
zinc oxide, titanium dioxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2400
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
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
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)			
BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626)			
ALUMINUM OXIDE (UNII: LM26O6933)			
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)			
MAGNESIUM SULFATE (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)			
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
Packaging			

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2400-4	113 g in 1 TUBE; Type 0: Not a Combination Product	12/27/2013	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part352	12/27/2013	

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(61995-2400)

Revised: 10/2014

The Hain Celestial Group, Inc.