ALBA BOTANICA MINERAL SUNSCREEN FF SPF30- 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 Mineral Sunscreen FF SPF30

Titanium Dioxide 2.0%

Zinc Oxide 14.5%

Helps prevent sunburns. If used as directed with other sun protection measures decreases the risk of skin cancer and skin aging caused by the sun. **Sun Protection Measures:** Spending time on the sun increases your risk of skin cancer and skin aging. To decrease the risk regulary use Broad Spectrum Sunscreen with SPF 15 or higher and other protective measures including: limit time in sun, especially from 10am to 2 pm, and wear long-sleeved shirts, pants, hats ans sunglasses.

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.

Sunscreen

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

Water, Caprylic/Capric Triglyceride, Dimethicone, Ethyhexyl Palmitate, Sorbitan Sesquioleate, Glycerin, Glyceryl Isostearate, Butyrospermum PARKII (Shea Butter), Polyglyceryl-3 Ricinoleate, Helianthus Annuus (Sunflower) Seed Oil (1), Simmondsia Chinensis (Jojoba) Seed Oil (1), Vitis Vinifera(Grape) Seed Oil, Aloe Barbadensis Leaf Juice (1), Calendula Officinalis Flower Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Tocopheryl Acetate, Alcohol, Magnesium Sulfate, Polyxydroxystearic Acid, Silica, Sodium Chloride, Benzyl Alcohol, Phenoxyethanol.



ALBA BOTANICA MINERAL SUNSCREEN FF SPF30

zinc oxide, titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.5 g in 100 g	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	2 g in 100 g	

Inactive Ingredients		
Ingredient Name	Strength	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)		
GLYCERIN (UNII: PDC6A3C0OX)		
DIMETHICONE (UNII: 92RU3N3Y10)		

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SHEA BUTTER (UNII: K49155WL9Y)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
SILICON DIOXIDE (UNII: ETJ7Z 6XBU4)	
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
ALOE (UNII: V5VD430YW9)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CHAMOMILE (UNII: FGL3685T2X)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GRAPE SEED OIL (UNII: 930MLC8XGG)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995- 2089-5	113 g in 1 TUBE; Type 0: Not a Combination Product	01/26/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/26/2017	

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(61995-2089)	

Revised: 4/2021 The Hain Celestial Group, Inc.