

BABY MINERAL SPF 50- zinc oxide 17.0 % 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.

AL00437 Baby Mineral SPF 50+

Active Ingredient Purpose

Zinc Oxide 17.0 % -----Sunscreen

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 6 months: ask a doctor. **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, and wear long-sleeved shirts, pants, hats and sunglasses.

Active Ingredient Purpose

Zinc Oxide 17.0 % -----Sunscreen

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.

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.

Inactive Ingredients

Aloe Barbadosensis Leaf Juice⁽¹⁾, Caprylic/Capric Triglyceride, Water (Aqua), Coconut Alkanes, Mica, Glycerin, Polyglyceryl-2 Sesquioleate, Brassica Alcohol, Polyglyceryl-3 Ricinoleate, Glyceryl Isostearate, Butyrospermum Parkii (Shea) Butter, Citrus Aurantium Dulcis (Orange) Peel Oil, Copernicia Cerifera (Carnauba) Wax, Juniperus Virginiana Oil, Camellia Sinensis Leaf Extract⁽¹⁾, Chamomilla Recutita (Matricaria) Flower Extract⁽¹⁾, Tocopheryl Acetate, Anisaldehyde, Benzyl Acetate, Biosaccharide Gum-1, C10-18 Triglycerides, Cetearyl Olivatate, Coco-Caprylate/Caprata, Glyceryl Caprylate, Polyhydroxystearic Acid, Potassium Hydroxide, Quartz, Sodium Anisate, Sodium Chloride, Sodium Levulinatate, Sorbitan Olivatate, Triethyl Citrate, Vanillin, Alcohol⁽¹⁾, Ethylhexylglycerin, Phenoxyethanol, Citronellol, Geraniol, Limonene, Linalool.

⁽¹⁾Certified Organic Ingredient

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.



BABY MINERAL SPF 50

zinc oxide 17.0% lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-0437
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
JUNIPERUS VIRGINIANA OIL (UNII: PAD4FN7P2G)	
O-ANISALDEHYDE (UNII: 7CP821WF2W)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LEVULINATE (UNII: VK44E1MQU8)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)	
SHEA BUTTER (UNII: K49155WL9Y)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM ANISATE (UNII: F9WFJ28MV9)	
VANILLIN (UNII: CHI530446X)	
.BETA.-CITRONELLOL, (+/-)- (UNII: 565OK72VNF)	
ALCOHOL (UNII: 3K9958V90M)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
GERANIOL (UNII: L837108USY)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
BIO SACCHARIDE GUM-1 (UNII: BB4PU4V09H)	
ORANGE OIL (UNII: AKN3KSD11B)	
CHAMOMILE (UNII: FGL3685T2X)	
BENZYL ACETATE (UNII: 0ECG3V79ZJ)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-2 SESQUIOLEATE (UNII: RHP7Q83BVB)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
COCONUT ALKANES (UNII: 1E5KJY107T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-0437-4	113 g in 1 TUBE; Type 0: Not a Combination Product	12/06/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/06/2019	

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.		081512382	manufacture(61995-0437)

Revised: 2/2021

The Hain Celestial Group, Inc.