

ALBA MINERAL TERRA TINT SPF15 BLAZE- zinc oxide 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 5.5%

Drug Facts

Active Ingredient	Purpose
Zinc Oxide 5.5%	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 sun exposure.

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 doctor if skin rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Children under 6 months: ask a doctor. Skin Protection Measures: Spending time in sun increases risk of skin cancer and early skin aging. To decrease risk, use sunscreen with broad spectrum SPF 15 or higher, limit time in sun, especially 10am-4pm, and wear hats and sunglasses.



100% vegetable ingredients, no animal testing.
 100% natural fragrance
 ©2012 The Alba Botanica Group, Inc.
 Meritt, NY 11767 MADE IN USA
 Net Wt. 4.2 g (1.5 oz)

PETA 100% V



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Inside Ply

Perforation

Drug Facts Continued...

Inactive Ingredients Cocoa Butter, Coconut Oil, Helianthus Annuus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Beeswax, Cetyl/Ceaproic Triglyceride, Cetyl Salicylate, Shea Butter, Iron Oxide (CI 77491), Mica (CI 77019), Menthyl Prenoate (Fragrance), Oleyl Oléate, Disolein Alkyl Dimethyl Sulfonium Chloride, Citrus Aurantium (Orange) Fruit Oil, Calendula Officinalis Flower Extract, Echinoside Pyruvate Extract, Silybum Matricariae Leaf/Steam Extract, Polyhydroxybutyrate Acetate, Polyhydroxy-3-Dimethylsilylate, Tocopheryl Acetate, Tetrahydrocyclopentadiene, Limonene, Linalool, Manganese Violet (CI 77742).
*Certified Organic Ingredient

Other Information
 Protect this product from excessive heat and direct sun.

Questions? Call (800) 658-7790 or visit www.albabetanica.com

Cont

Cream. Apply liberally 15 minutes before sun exposure
 Sunscreen

For external use only. Do not use on damaged skin. When using this product keep out of eyes.

Helps prevents sunburns. If uses as directed with other sun protection measures, decreases risk of skin cancer and early skin aging caused by sun exposure

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

Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Iron Oxides (CI 77491), Mica (CI 77019), Mentha Piperita (Peppermint) Oil (1), Olea Europaea (Olive) Fruit Oil, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Stevia Rebaudiana Leaf/Stem Extract (1), Polyhydroxystearic Acid, Polyglyceryl-3 Diisostearate, Tocopheryl Acetate, Triethoxycaprylylsilane, Limonene, Linalool.

(1) Certified Organic Ingredient

ALBA MINERAL TERRA TINT SPF15 BLAZE

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
COCONUT OIL (UNII: Q9L0O73W7L)	
CANDELILLA WAX (UNII: WL0328HX19)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
RICE BRAN (UNII: R60QEP13IC)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA PURPUREA ROOT (UNII: OS64WTR4KU)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
SUNFLOWER OIL (UNII: 3W1JG795YJ)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MANGANESE VIOLET (UNII: 72M48QQV8Q)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2500-1	4.2 g in 1 BOTTLE; Type 0: Not a Combination Product	08/06/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/06/2013	

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(61995-2500)

Revised: 9/2014

The Hain Celestial Group, Inc.