

ALBA MINERAL TERRA TINT SPF15 GARNET- 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.

Zinc Oxide 5.5%

Sunscreen

Cream. Apply liberally 15 minutes before sun exposure

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

Helps prevent sunburn. 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 or contact Poison Center right away.

Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Beeswax, Caprylic/Capric Triglyceride, Mica, Titanium Dioxide, Oryza Sativa (Rice) Bran Wax, 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, Iron Oxides (CI 77491), Iron Oxides (CI 77499), Manganese Violet.

(1)-Certified Organic Ingredients.

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 rash ever 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-2pm, and wear hats and sunglasses.	

100% vegetable ingredients, no animal testing.
 Made with natural oils.
 ©2012 The Body Company, Inc.
 Merills, NY 11767 MADE IN USA
 Net Wt. 4.2 oz (117.6 g)

alba
 BOTANICA
 mineral
 terra
 tints
 spf
 15
 broad spectrum
 garnet

0 77320 77335 2 1 PCT. 10624

Inside Ply

Perforation

Drug Facts Continued...	
Inactive Ingredients Cocoa Butters, Ecovonol Oil, Helianthus Annuus (Sunflower) Seed Oil, Eucalyptus Caribaea (Candellilla) Wax, Caprylic/Capric Triglyceride, Resinoid, Mangrove Water (27742), Oryza Sativa (Rice) Bran Wax, Iron Oxides (27742/3), Maritima Pimenta (Peppercorn) Oil, Cassia Tarpusa (Tina) Fruit Oil, Calendula Officinalis Flower Extract, Galbanum Purpurae Extract, Sida Robustioris Leaf/Stem Extract ¹ , Polyhydroxybutyrate Acid, Polyglyceryl-3 Dimethylsiloxylsuccinate, Tocopheryl Acetate, Triethoxycaprylylsilane, Ultraviolet Filters ² , Iron Oxides (27742), Zinc Oxide (27742), Titanium Dioxide (27781) ¹ Certified Organic Ingredient	
Other Information Protect this product from excessive heat and direct sun	
Questions? Call (800) 658-7790 or visit www.albabotanica.com	

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2535
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
RICE BRAN (UNII: R60QEP13IC)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
MICA (UNII: V8A1AW0880)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MANGANESE VIOLET (UNII: 72M48QQV8Q)	
COCONUT OIL (UNII: Q9L0O73W7L)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CANDELILLA WAX (UNII: WL0328HX19)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2535-1	4.2 g in 1 JAR; Type 0: Not a Combination Product	08/16/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/16/2013	

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(61995-2535)

Revised: 10/2014

The Hain Celestial Group, Inc.