

ALBA TERRATINT GARNET SPF 15 LIP BALM- zinc oxide stick
Autumn Harp, 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 TerraTint Garnet SPF 15 Lip Balm

Active Ingredient

Zinc Oxide 5.5%

Purpose

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-2pm, and wear hats and sunglasses.

Inactive Ingredients

Cocos Nucifera (Coconut) Oil, Helianthus Annuus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Caprylic/Capric Triglyceride, Beeswax, Manganese Violet (CI 77742), Oryza Sativa (Rice) Bran Wax, Iron Oxides (CI 77491), Mentha Piperita (Peppermint) Oil*, Olea Europaea (Olive) Fruit Oil, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Stevia Rebaudiana (Stevia) Leaf/Stem Extract*, Polyhydroxystearic Acid, Polyglyceryl-3 Diisostearate, Tocopheryl Acetate, Triethoxycaprylylsilane, Limonene*, Linalool*, Iron Oxides (CI 77499), Mica (CI 77019), Titanium Dioxide (CI 77891). ***Certified Organic Ingredient**

Other Information

Protect this product from excessive heat and direct sun

Questions?

Call (888) 659-7730 or visit www.albabotanica.com

Principal Display Panel

Image Components

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 5.5%	Sunscreen
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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 years of age: ask a doctor. Sun 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, look for shade, wear especially 10am-2pm, and wear hats and sunglasses.	

100% vegetarian ingredients, no animal testing.

Manufactured for distribution by:
©2012 The Hain Celestial Group, Inc.
Melville, NY 11747 MADE IN USA
Net Wt 4.2 g e 0.15 oz

alba
BOTANICA

mineral

terra
tints

spf
15
broad spectrum

garnet

PEEL HERE

0 77320 77535 2

Inside Ply

Perforation

Drug Facts Continued...	
Inactive Ingredients Cores/Nuclei: Coconut Oil, Helianthus Annuus (Sunflower) Seed Oil, Euphorbia Cerifera (Candelilla) Wax, Cetylalcohol, Triolein, Beeswax, Monopropylene Glycol (77742), Oryza Sativa (Rice Bran) Wax, Iron Oxides (77491), Mentha Poeniata (Peppermint) Oil, Olea Europaea (Olive) Fruit Oil, Galinella Officinalis Flower Extract, Echinacea Purpurea Extract, Stevia Rebaudiana Leaf/Green Extract, Polyhydroxybutyrate Adipic Polyglycolic Acid (PHBA), Tocopherol Acetate, Hydroxypropylstarch, Linoleic Acid, Iron Oxides (77491), Mica (77013), Titanium Dioxide (77891). *Certified Organic Ingredient.	
Other Information Protect this product from excessive heat and direct sun.	
Questions? Call (800) 659-7733 or visit www.albabotanica.com	

ALBA TERRATINT GARNET SPF 15 LIP BALM

zinc oxide stick				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0304	
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)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
CANDELILLA WAX (UNII: WL0328HX19)				
YELLOW WAX (UNII: 2ZA36H0S2V)				
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)				
MANGANESE VIOLET (UNII: 72M48QQV8Q)				
RICE BRAN (UNII: R60QEP13IC)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
MICA (UNII: V8A1AW0880)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)				
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
FERROSFERRIC OXIDE (UNII: XM0M87F357)				
LIMONENE, (+/-)- (UNII: 9MC3I34447)				
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)				
ECHINACEA PURPUREA (UNII: QI7G114Y98)				
LINALOOL, (+/-)- (UNII: D81QY6I88E)				
Product Characteristics				
Color	pink	Score		
Shape		Size		
Flavor	PEPPERMINT	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0304-1	4.2 g in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/01/2012	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0304)

Revised: 9/2013

Autumn Harp, Inc.