

ALBA TERRATINT BLAZE 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 Blaze 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, Beeswax, Caprylic/Capric Triglyceride, Oryza Sativa (Rice) Bran Wax, Iron Oxides (CI 77491), Mica (CI 77019), Mentha Piperita (Peppermint) Oil*, Olea Europaea (Olive) Fruit Oil, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Stevia Rebaudiana (Stevia) Leaf Extract*, Polyhydroxystearic Acid, Polyglyceryl-3 Diisostearate, Tocopheryl Acetate, Triethoxycaprylsilane, Limonene*, Linalool*, Manganese Violet. * **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


Outside Ply

h Area

Drug Facts	
Active Ingredient	Purpose
Zinc Oxide 5.6%	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, skin under 6 months, Sun Protection: Moderate. 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% 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
blaze

PEEL HERE
 U8750002

 0 77320 77500 0

Inside Ply

Perforation

Drug Facts Continued...
Inactive Ingredients Cera Niacin (Compound of Niacin, Nicotinamide, Nicotinic Acid), Seed Oil, Euphorbia Dangle (Candelilla) Wax, Rosehip, Caprylic/Capric Triglyceride, Oryza Sativa (Rice) Bran Wax, Iron Oxides (CI 77491), Mica (CI 77019), Mentha Piperita (Peppermint) Oil*, Citrus Aurantium (Grove) Fruit Oil, Galinula Officinalis (Ranch) Extract, Echinosia Purpurea Extract, Stevia Rebaudiana Leaf/Stein Extract, Polyhydroxylated Acid, Polyglyceryl-3 Distearate, Tocopherol Acetate, Trihydroxypropylsilane, Limonene*, Unlabeled*, Manganese Violet (CI 77742), *Certified Organic Ingredient
Other Information Protect this product from excessive heat and direct sun.
Questions? Call (866) 698-7731 or visit www.albabotanica.com

ALBA TERRATINT BLAZE SPF 15 LIP BALM

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0305
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)	
RICE BRAN (UNII: R60QEP13IC)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
MICA (UNII: V8A1AW0880)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
TRIETHOXYCAPRYL YLSILANE (UNII: LDC331P08E)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
MANGANESE VIOLET (UNII: 72M48QQV8Q)	
LIMONENE, (+/-)- (UNII: 9MC3I34447)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
POLYGLYCERYL-3 DIISO STEARATE (UNII: 46P231IQV8)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Product Characteristics

Color	purple	Score	
Shape		Size	
Flavor	PEPPERMINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0305-1	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(51514-0305)

Revised: 9/2013

Autumn Harp, Inc.