

**ALBA VERY EMOLLIENT SUNSCREEN LIP CARE SPF25- octocrylene, octinoxate, octisalate, 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 Very Emollient Sunscreen Lip Care SPF25

Active Ingredient

Octocrylene 10.0%

Ethylhexyl Methoxycinnamate 7.5%

Zinc Oxide 3.7%

Ethylhexyl Salicylate 1.0%

Purpose

Sunscreen

Sunscreen

Sunscreen

Sunscreen

Uses

- Helps prevent sunburn

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. **Sun Protection**

Measures: Spending time in the sun increases your risk of skin cancer and early skin aging.

Directions

Apply liberally 15 minutes before sun exposure. Reapply at least every 2 hours. Children under 6 months: ask a doctor.

Inactive Ingredients

Beeswax*, Helianthus Annuus (Sunflower) Seed Oil*, Simmondsia Chinensis (Jojoba) Seed Oil*, Olea Europaea (Olive) Fruit Oil*, Ricinus Communis (Castor) Seed Oil*, C12-15 Alkyl Benzoate, Flavor*, Euphorbia Cerifera (Candelilla) Wax, Copernicia Cerifera (Carnauba) Wax*, Butyrospermum Parkii (Shea Butter)*, Theobroma Cacao (Cocoa) Seed Butter*, Glycine Soya (Soybean) Oil, Oenothera Biennis (Evening Primrose) Oil, Aloe Barbadensis Leaf Extract*, Calendula Officinalis Flower Extract, Echinacea Purpurea Extract, Allantoin, Ammonium Glycyrrhizate, Tocopherol, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Iron Oxides (CI 77491), * **Certified Organic Ingredient**

Other Information

Protect this product from excessive heat and direct sun

Questions?

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

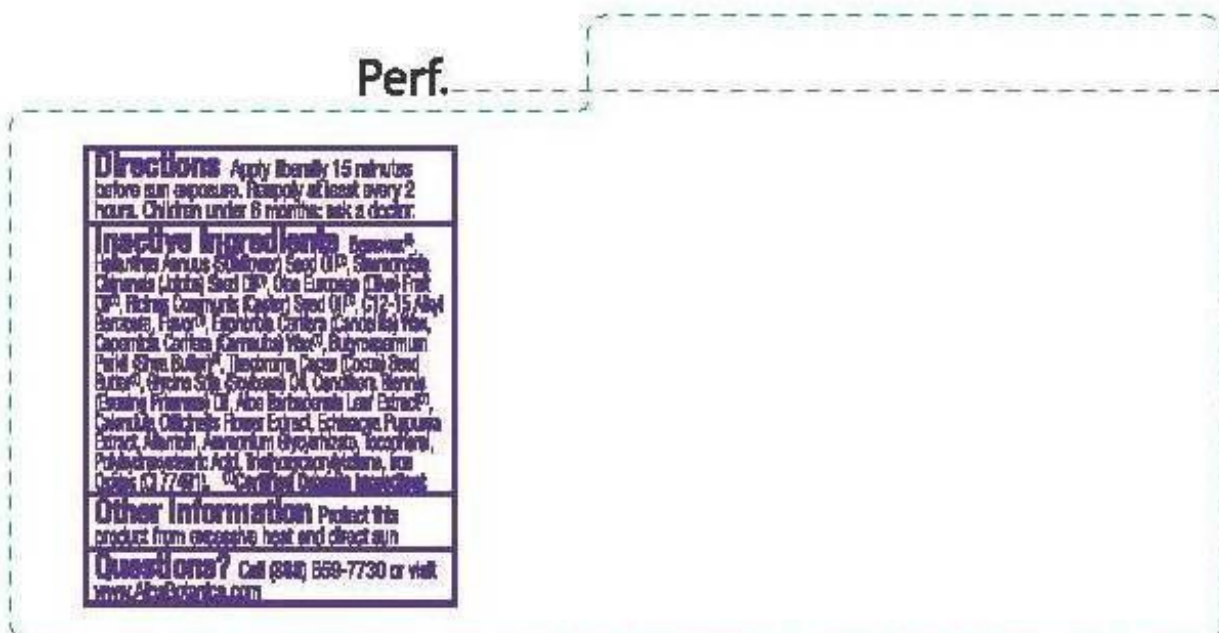
Principal Display Panel

Image Components



Bottom Ply

Perf.





ALBA VERY EMOLLIENT SUNSCREEN LIP CARE SPF25

octocrylene, octinoxate, octisalate, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51514-0306
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10.0 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	1.0 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC Oxide - UNII:SOI2LOH54Z)	ZINC OXIDE	3.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
YELLOW WAX (UNII: 2ZA36H0S2V)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
JOJOBA OIL (UNII: 724GKU717M)	
CASTOR OIL (UNII: D5340Y2I9G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
VANILLA (UNII: Q74T35078H)	
CANDELILLA WAX (UNII: WL0328HX19)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SHEA BUTTER (UNII: K49155WL9Y)	
COCOA BUTTER (UNII: 512OYT1CRR)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SOYBEAN OIL (UNII: 241ATL177A)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
ALLANTOIN (UNII: 344S277G0Z)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color	pink	Score	
Shape		Size	
Flavor	VANILLA	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51514-0306-1	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	04/01/2012	

Labeler - Autumn Harp, Inc. (064187883)

Establishment

Name	Address	ID/FEI	Business Operations
Autumn Harp, Inc.		064187883	manufacture(51514-0306)

Revised: 9/2013

Autumn Harp, Inc.