

**ALBA BOTANICA UN-PETROLEUM VANILLA SPF18 LIP BALM - ethylhexyl dimethyl paba, benzophenone-3 stick**

**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.*

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**Drug Facts**

Ethylhexyl Dimethyl PABA 7.5%

Benzophenone-3 5.0%

Sunscreen

Helps prevent sunburn

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 a doctor if skin rash occurs.

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

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

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

Ricinus Communis (Castor) Seed Oil, Beeswax, Euphorbia Cerifera (Candelilla) Wax, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil (1), Lanolin, Copernicia Cerifera (Carnauba) Wax, Glycine Soja (Soybean) Oil, Oenothera Biennis (Evening Primrose) Oil, Olea Europaea (Olive) Fruit Oil, Echinacea Purpurea Extract, Vanilla Planifolia Fruit Extract, Ammonium Glycyrrhizate, Tocopherol, Tocopheryl Acetate.

(1) Certified Organic Ingredient

Questions? Call 888-659-7730 or visit [www.AlbaBotanica.com](http://www.AlbaBotanica.com)

**Drug Facts  
(Under Wrap)**

**alba**  
un-petro-leum  
PLANT-BASED LIP CARE  
VANILLA

WITH HEALING VITAMIN E PROTECTIVE  
SUNSCREEN AND NATURALLY SOOTHING  
PLANT EXTRACTS.

SPF 18 lip balm

NET WT 0.56 oz e 4.2 g

0 77320 00005 8

Manufactured by distribution by ©2011 The Herb Channel Group, Inc.  
MADE IN THE USA

**Drug Facts**

**Active Ingredient Purpose**

Erythryl Dimethyl PABA 7.5% ..... Sunscreen  
Benzophenone-3 3.0% ..... 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 a doctor if skin rash occurs. Keep out of reach of children. If swallowed, get medical help or contact a 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.

LAB77302DW001

**Bottom Ply**

**Drug Facts Cont.  
(Over Wrap)**

**Inactive Ingredients** Ricinus Communis (Castor) Seed Oil, Beeswax, Euphorbia Cerifera (Candelilla) Wax, Cocos Nucifera (Coconut) Oil, Simmondsia Chinensis (Jojoba) Seed Oil, Lanolin, Copernicia Caribaea (Carnauba) Wax, Glycine Soja (Soybean) Oil, Oenothera Biennis (Evening Primrose) Oil, Olea Europaea (Olive) Fruit Oil, Echinacea Purpurea Extract, Vanilla Planifolia Fruit Extract, Ammonium Glycinate, Tocopherol, Tocopheryl Acetate. **® Certified Organic Ingredient**

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

**Questions?** Call (888) 659-7730 or visit [www.AlaBotanica.com](http://www.AlaBotanica.com)



ethylhexyl dimethyl paba, benzophenone-3 stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61995-2921
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PADIMATE O (UNII: Z11006CMUZ) (PADIMATE O - UNII:Z11006CMUZ)	PADIMATE O	7.5 g in 100 g
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	5.0 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340Y2I9G)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CANDELILLA WAX (UNII: WL0328HX19)	
JOJOBA OIL (UNII: 724GKU717M)	
LANOLIN (UNII: 7EV65EAW6H)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SOYBEAN OIL (UNII: 241ATL177A)	
EVENING PRIMROSE OIL (UNII: 3Q9L08K71N)	
OLIVE OIL (UNII: 6UYK2WIW1E)	
ECHINACEA PURPUREA (UNII: QI7G114Y98)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
COCONUT OIL (UNII: Q9L0O73W7L)	
VANILLA (UNII: Q74T35078H)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2921-1	1 in 1 CARTON		
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	11/02/2011	

**Labeler** - The Hain Celestial Group, Inc. (858894996)

**Establishment**

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture

Revised: 5/2012

The Hain Celestial Group, Inc.