

ALBA SUNBLOCK NATURAL LAVENDER SPF 45 - homosalate, octocrylene, ethylhexyl methoxycinnamate, ethylhexyl salicilate, titanium dioxide 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.

Drug Facts

ACTIVE INGREDIENTS

Homosalate 10.0%

Octocrylene 10.0%

Ethylhexyl Methoxycinnamate 7.5%

Ethylhexyl Salicilate 5.0%

Titanium Dioxide 2.0%

USES

- Helps prevent sunburns
- Higher SPF gives more sunburn protection
- Apply liberally as needed 15 to 20 minutes before sun exposure
- Reapply as needed or after swimming, perspiring or towel drying
- Children under 6 months of age: ask doctor

WARNINGS

For external use only. When using this product keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if rash or irritation develops and lasts. Keep out of reach of children. If swallowed, get medical help or contact Poison Center right away.

QUESTIONS?

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

100% Vegetarian Ingredients

No Animal Testing

Alba Botanica

The Hain Celestial Group, Inc.

Melville, NY 11747

Made in the U.S.A.

v.11

- Make background rays have more contrast



Resource #(s): 003931		Date: 11/14/2009	Version: 11	
File Name: 00393-LAV SPF 45.ai			Designer: BN	
Size Specs: 50mm dia. x 103mm			bnd Job#: 36	
Decoration: Direct Tube Offset		PMS Colors:		Approval Signoff:
Materials: Pearlized White		PMS 2645c		<input type="checkbox"/>
Printing: 5C Spot + 1 Silkscreen		PMS 268c		<input type="checkbox"/>
Finishing: N/A		PMS 7455c		<input type="checkbox"/>
DieLine: 50mm dia. x 103mm		SILKSCREEN PMS 233c		<input type="checkbox"/>
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with SCF SEAL



v.11
2009.11.14

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2393
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	10 g in 100 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	10 g in 100 g
Octinoxate (UNII: 4Y5P7MUD51) (Octinoxate - UNII:4Y5P7MUD51)	Octinoxate	7.5 g in 100 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	5.0 g in 100 g
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	2.0 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2393-4	113 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/28/2009	

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

Establishment

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

Revised: 7/2010

The Hain Celestial Group, Inc.