

ALBA VE SUNSCREEN SPORT SPF45- homosalate, octinoxate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane, titanium dioxide lotion

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.

Active Ingredient

Homosalate - 10.0%

Octocrylene - 10.0%

Ethyl Methoxycinnamate - 7.5

Ethylhexyl Salicylate - 5.0%

Butyl Methoxydibenzoylmethane - 2.0%

Titanium Dioxide - 1.0%

Apply liberally 15 minutes before sun exposure. Reapply after 80 minutes of swimming or sweating, immediately after towel drying and at least every 2 hours.

Sunscreen

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.

Water, Glycerin, Glyceryl Stearate SE, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, VP/Hexadecene Copolymer, Caprylic/Capric Triglyceride, Hydrogenated Palm Cernel Oil, Aloe Barbadensis Leaf Juice(1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Calendula Officinalis Flower Extract (1), Lavandula Angustifolia (Lavender) Extract (1), Ginkgo Biloba Leaf Extract, Panax Ginseng Root Extract, Cetearyl Alcohol, Cetearyl Oliviate, Polysorbate 60, Lecithin, Silica, Sodium Chloride, Sodium Stearoyl Glutamate, Sorbitan Oliviate, Tocopheryl Acetat, Xanthan Gum, Alcohol (1), Benzyl Alcohol, Ethylhexylglycerin, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate.

(1) Certified Organicf Ingredient

Helps prevents sunburns. If used as directed with other sun protection measures, decreases risk of skin cancer and early skin aging caused by sun exposure. Skin Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including: limit time in sun, especially from 10am to 2pm, and wear long sleeved shirts, pants, hats and sunglasses.

Very emollient and instant-on waterproof sun protection.

Key Facts	Additional Information
Active Ingredients Fragrance Homosalate 5.0% Octinoxate 3.0% Ethylhexyl salicylate 2.0% Octocrylene 3.0% Butyl methoxydibenzoylmethane 3.0% Titanium dioxide 12.0%	Additional Information on back of packaging. Very emollient, instant-on waterproof sun protection. For use on face and body. Avoid contact with eyes. Do not use if you are pregnant or breastfeeding. For more information, visit www.alba.com .
SPF 45 - Broad spectrum sun protection. SPF 45 provides 90% protection against UVB rays. Broad spectrum sun protection also protects against UVA rays.	Water Resistant - Up to 80 minutes.
Microbiological - For added security, this cream undergoes a microbiological test to ensure it is free from harmful bacteria.	Other Information - Contains fragrance.
Directions - Apply liberally to clean, dry skin before sun exposure. Reapply every 2 hours, or more often if you are sweating or swimming. For more information, visit www.alba.com .	Caution - Keep out of reach of children.
©2015 Alba Laboratories, Inc. Alba Laboratories, Inc. Manufactured by: Alba Laboratories, Inc. Salisbury, MD 21834, Product of USA. 100% VEGAN	



very emollient sunscreen

sport

water resistant (80 minutes)
Microbiological
gluten free



no parabens, sulfates, or other nasties

100% vegetarian ingredients

NET WT 1.76 g (4 oz)



7.15 cm

103 ± 1mm

ALBA VE SUNSCREEN SPORT SPF45

homosalate, octinoxate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2039
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
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	10 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0K00R)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
LAVANDULA ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GINKGO (UNII: 19FUJ2C58T)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2039-4	113 g in 1 TUBE; Type 0: Not a Combination Product	05/20/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/20/2014	

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

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

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture(61995-2039)

Revised: 11/2014

The Hain Celestial Group, Inc.