

**ALBA BOTANICA NATURAL VERY EMOLLIENT SUNSCREEN SPORT SPRAY SPF40 -
homosalate, ethylhexyl methoxycinnamate, octocrylene, ethylhexyl salicylate, butyl
methoxydibenzoylmethane 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.

Drug Facts

Homosalate 12.0%

Ethylhexyl Methoxycinnamate 7.5%

Octocrylene 7.0%

Ethylhexyl Salicylate 5.0%

Butyl Methoxybenzoylmethane 3.0%

Sunscreen

- Helps prevent sunburn

For external use only. Do not use on damaged or broken skin. 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

Apply liberally 15 minutes before sun exposure. Reapply after 80 min of swimming or sweating, after towel drying and at least every two hrs. 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. To decrease a risk, regularly use a Sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including: limit time in sun, especially 10am- 2pm, wear long- sleeved shirts, pants, hats and sunglasses.

Aqua (Water), Aloe Barbadensis Leaf Juice (1), Glycerin, VP/Hexadecene Copolymer, Sodium Stearoyl Glutamate, Calendula Officinalis Flower Extract (1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Olea Europaea (Olive) Leaf Extract, Panax Ginseng Root Extract (1), Ginkgo Biloba Root Extract, Cetyl Alcohol, Citric Acid, Glyceryl Stearate SE, Potassium Cetyl Phosphate, Sodium Chloride, Tocopheryl Acetate, Xanthan Gum, Alcohol (1), Benzyl Alcohol, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate.

(1) Certified Organic Ingredient

888-659-7730, www.AlbaBotanica.com

alba
BOTANICA

natural very
emollient
sunscreen

natural protection
sport spray

water resistant (80 minutes)
quick dry lotion
paraben free

WATER RESISTANT
SPF
40
WATER RESISTANT



Net Wt 113 g e 4 oz

Drug Facts

Active Ingredient: Puzozone

Homocastole 12.0 %.....Sunscreen
 Ethylhexyl Methoxycinnamate 7.5 %
 Octocrylene 7.0 %.....Sunscreen
 Ethylhexyl Salicylate 5.0 %.....Sunscreen
 Butyl Methoxydibenzoylmethane 3.0%.....Sunscreen

Uses • Helps prevent sunburn

Warnings For external use only. Do not use on damaged or broken skin. Keep out of eyes. Rinse with water to remove. Stop use and seek doctor if rash occurs. Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Directions Apply liberally 15 min. before sun exposure. Reapply after 80 mins. of swimming or sweating, after towel drying and at least every 2 hrs. Children under 6 mos. ask a doctor. Sun Protection Measures: Spending time in sun increases 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 10am - 2pm, wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients: Aqua (Water), Glycolin, VP-Ascorbic Acid Copolymer, Sodium Stearyl Ethoxycarbonate, Dimethylsiloxane, Avocado Germantolene Leaf Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Olea Europaea (Olive Leaf Extract, Ginkgo Biloba Leaf Extract, Prunus Sibirica Leaf Extract, Coptis Alcockii, Citrus Acid, Glycerol Stearate SE, Potassium Glycid Phosphate, Sodium Chloride, Tocopheryl Acetate, Xanthan Gum, Alcohol, Benzyl Alcohol, Phenylsiloxane, Polysilbum Sulfate, Sodium Benzoate, Polymethyl Dimethyl Siloxane

Manufactured by: ©2011 The Hale Collection Group, Inc.
 Merrick, NY 11767 (516) 669-7700 www.halecollection.com
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ALBA BOTANICA NATURAL VERY EMOLLIENT SUNSCREEN SPORT SPRAY

SPF40

homosalate, ethylhexyl methoxycinnamate, octocrylene, ethylhexyl salicylate, butyl methoxydibenzoylmethane lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2383
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	12 g in 100 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7.0 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5.0 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3.0 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
GINKGO (UNII: 19FUJ2C58T)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2383-4	113 g in 1 BOTTLE, SPRAY		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/29/2011	

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.