

AL0038502 ALBA TROPICAL FRUIT KIDS SUNSCREEN SPF40- homosalate, octocrylene, ethylhexyl salicylate, avobenzone spray
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.

Alba Botanica Kids Sunscreen Spray Lotion SP F40

Avobenzone -3%

Homosalate -12.0%

Octocrylene - 7.0%

Octyl Salicylate - 5.0%

Sunscreen

- Helps prevent sunburn. If used as directed with other sun protection measures, decreases risk of skin cancer and early skin aging caused by sun.

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), Caprylic/Capric Triglyceride, Glycerin, Aloe Barbadensis Leaf Juice (1), VP/Hexadecene Copolymer, Sodium Stearoyl Glutamate, Dimethicone, Citrus Aurantium Dulcis (Orange) Peel Oil, Glycine Soja (Soybean) Oil, Calendula Officinalis Flower Extract (1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Ginkgo Biloba Root Extract, Olea Europaea (Olive) Leaf Extract, Panax Ginseng Root Extract (1), Tocopheryl Acetate, Alcohol (1), A-Terpinyol Acetate, Cetyl Alcohol, Citric Acid, Dimethylhydroxy Furanone, Glyceryl Stearate SE, Nonanal, Potassium Cetyl Phosphate, Sodium Chloride, Vanillin, Xanthan Gum, Benzyl Alcohol, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Limonene.

(1) Certified Organic Ingredient

888-659-7730, www.AlbaBotanica.com



Drug Facts

Active Ingredient	Percentage	Function
PABA	3%	Sunscreen
Homosalate	12%	Sunscreen
Octisalate	5%	Sunscreen
Octocrylene	7%	Sunscreen

Uses - Helps prevent sunburn - If used as directed with other sun protection measures (see Warnings), decreases risk of skin cancer and early skin aging caused by the sun.

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 min. 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), Copolymerized Triethylsiloxane, Glyceryl Mono Stearate, Caprylic/Capric Triglyceride, Glyceryl Mono Stearate, Cetearyl Alcohol, Dimethicone, Citrus Aurantium Dulcis (Orange) Peel Oil, Eucalyptus Globulus (Eucalyptus) Oil, Calendula Officinalis Flower Extract, Chamomilla Recutita (Chamomile) Flower Extract, Ginkgo Biloba Leaf Extract, Citrus Aurantium (Bitter) Leaf Extract, Pappas Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, A-Terpinyl Alcohol, Citric Acid, Dimethylsiloxane, Pentaerythritol, Potassium Sorbate, Sodium Benzoate, Limonene, *Quaternized Organic Inorganic



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PRESS DIRECTION

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AL0038502 ALBA TROPICAL FRUIT KIDS SUNSCREEN SPF40

homosalate, octocrylene, ethylhexyl salicylate, avobenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2085
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
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	7 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
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)	
ORANGE OIL (UNII: AKN3KSD11B)	
SOYBEAN OIL (UNII: 241ATL177A)	
TERPINYL ACETATE (UNII: NIT9SZT3D7)	
DIMETHYLHYDROXY FURANONE (UNII: 20PI8YZP7A)	
NONANAL (UNII: 2L2WBY9K6T)	
VANILLIN (UNII: CHI530446X)	

LIMONENE, (+)- (UNII: GFD7C86Q1W)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2085-4	118 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	09/13/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/13/2016	

Labeler - The Hain Celestial Group, Inc. (117115556)

Registrant - The Hain Celestial Group, Inc. (081512382)

Establishment

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		081512382	manufacture(61995-2085)

Revised: 4/2021

The Hain Celestial Group, Inc.