

ALBA BOTANICA KIDS SUNSCREENTROPICAL FRUIT SPF45- avobenzone, homosalate, octocrylene, octyl salicylate 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.

Alba Botanica Kids Sunscreen Tropical Fruit SPF45 AL00399

Active Ingredient

Avobenzone - 3.0%

Homosalate - 10.0%

Octocrylene - 10.0%

Octyl Salicylate - 5.0%

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, Cetyl Alcohol, Glycerin, Glyceryl Stearate SE, Dimethicone, Caprylic/Capric Triglyceride, VP/Hexadecene Copolymer, Cetearyl Alcohol, Citrus Aurantium Dulcis (Orange) Peel Oil, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice(1), Calendula Officinalis Flower Extract (1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Ginkgo Biloba Leaf Extract, Lavandula Angustifolia (Lavender) Extract (1), Panax Ginseng Root Extract, Tocopheryl Acetate, Alcohol (1), A-Terpinyl Acetate, Cetearyl Alcohol, Cetearyl Oliviate, Citric Acid, Dimethylhydroxy Furanone, Nonanal, Polysorbate 60, Sodium Chloride, Sodium Stearoyl Glutamate, Sorbitan Oliviate, Vanillin, Xanthan Gum, Benzyl Alcohol, Potassium Sorbate, Sodium Benzoate, Limonene.

(1) Certified Organic Ingredient

Helps prevent 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.



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 avobenzene, homosalate, octocrylene, octyl salicylate lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2099
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: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
	OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
	AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
.ALPHA.-TERPINYL ACETATE, (+/-)- (UNII: 9RXE019F2J)	
LAVANDULA ANGUSTIFOLIA FLOWER (UNII: 19AH1RAF4M)	
ALCOHOL (UNII: 3K9958V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	

SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
ORANGE OIL (UNII: AKN3KSD11B)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
ASIAN GINSENG (UNII: CUQ3A77YXI)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
SOYBEAN OIL (UNII: 241ATL177A)
CETYL ALCOHOL (UNII: 936JST6JCN)
DIMETHICONE (UNII: 92RU3N3Y1O)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CHAMOMILE (UNII: FGL3685T2X)
XANTHAN GUM (UNII: TTV12P4NEE)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
POLYSORBATE 60 (UNII: CAL22UVI4M)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
GINKGO (UNII: 19FUJ2C58T)
CETEARYL OLIVATE (UNII: 58B69Q84JO)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
SORBITAN OLIVATE (UNII: MDL271E3GR)
SODIUM BENZOATE (UNII: OJ245FE5EU)
DIMETHYLHYDROXY FURANONE (UNII: 20PI8YZP7A)
NONANAL (UNII: 2L2WBY9K6T)
LIMONENE, (+/-)- (UNII: 9MC3I34447)
VANILLIN (UNII: CHI530446X)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2099-4	113 g in 1 TUBE; Type 0: Not a Combination Product	10/11/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/11/2017	

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(61995-2099)

Revised: 4/2021

The Hain Celestial Group, Inc.