

ALBA BOTANICA SPF 50 SUNSCREEN- avobenzene, homosalate, octocrylene, octisalate 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 SPF 50 Sunscreen Lotion

Avobenzene 3%

Homosalate 10%

Octocrylene 10%

Octisalate 5%

● Apply liberally 15 minutes before sun exposure ● Reapply: ● after 80 minutes of swimming or sweating ● immediately after towel drying ● at least every 2 hours ● Children under 6 months of age: ask a doctor

● **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 am - 2 pm
- wear long-sleeved shirts, pants, hats, and sunglasses

Sunscreen

For external use only. Do not use on broken or damaged skin. When using this product, keep out of eyes. Rinse with water to remove. Stop use and ask a doctor if skin rash occurs. If swallowed, get medical help or contact a Poison Control Center right away.

Keep out of reach of children.

Water (Aqua), Butyloctyl Salicylate, Dodecane, VP/Hexadecene Copolymer, Polyglyceryl-10 Pentastearate, Glycerin, Cetyl Alcohol, Glyceryl Stearate SE, Glyceryl Oleate Citrate, Behenyl Alcohol, Phenoxyethanol, Citrus Aurantium Dulcis (Orange) Peel Oil, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice (1), Tocopheryl Acetate, Caprylic/Capric Triglyceride, Cetearyl Oliviate, Citric Acid, Decane, Dimethylhydroxy Furanone, Nonanal, Nonane, Potassium Hydroxide, Sodium Phytate, Sodium Stearoyl Lactylate, Solanum Tuberosum (Potato) Starch, Sorbitan Oliviate, Terpinel Acetate, Vanillin, Alcohol (1), Ethylhexylglycerin, Potassium Sorbate, Sodium Benzoate, Limonene

(1) Certified Organic Ingredient

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

biodegradable
& cruelty free

botanically moisturizing,
non-greasy sun protection

alba
BOTANICA®

kids

broad spectrum spf

50



tropical
fruit
sunscreen lotion

water resistant (80 minutes)
tear free
free of oxybenzone
& octinoxate

3 fl. oz. (89 ml)



Drug Facts

Active ingredients	Purpose
Avobenzone 3% w/w.....	Sunscreen
Homosalate 10% w/w.....	Sunscreen
Octocrylene 10% w/w.....	Sunscreen
Octisalate 5% w/w.....	Sunscreen

Uses • Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the 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.
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 a Poison Control Center right away.

Directions • Apply liberally 15 minutes before sun exposure
• Reapply: • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • Children under 6 months: ask a doctor.
• Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease risk, regularly use a sunscreen with Broad Spectrum SPF 15 or higher and other protective measures including:
• limit time in sun, especially from 10 a.m. - 2 p.m. • and wear long-sleeved shirts, pants, hats and sunglasses.

Inactive ingredients

Water (Aqua), Butyloctyl Salicylate, Dodecane, VP/ Hexadecene Copolymer, Polyglyceryl-10 Pentastearate, Glycerin, Cetyl Alcohol, Glyceryl Stearate SE, Glyceryl Oleate Citrate, Behenyl Alcohol, Phenoxyethanol, Citrus Aurantium Dulcis (Orange) Peel Oil, Glycine Soja (Soybean) Oil, Aloe Barbadensis Leaf Juice[®], Tocopherol Acetate, Caprylic/Capric Triglyceride, Cetearyl Olivate, Citric Acid, Decane, Dimethylhydroxy Furanone, Nonanol, Nonane, Potassium Hydroxide, Sodium Phylate, Sodium Stearoyl Lactylate, Solanum Tuberosum (Potato) Starch, Sorbitan Olivate, Terpinol Acetate, Vanillin, Alcohol[®], Ethylhexylglycerin, Potassium Sorbate, Sodium Benzoate, Limonene
[®]Certified Organic Ingredient

Other information

Protect this product from excessive heat and direct sun. Store in room temperature 59°F - 86°F.

Questions? Call (888) 659-7730 or visit www.albaboranica.com

*biodegradable formula

NO
oxybenzone, octinoxate,
animal testing, synthetic fragrances,
artificial colors, parabens, phthalates,
sulfates or petrolatum
100% vegetarian ingredients

MANUFACTURED BY:
The Hain Celestial Group, Inc.
Lake Success, NY 11042 USA
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Made in USA with globally sourced materials
TUB003994L014



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avobenzone, homosalate, octocrylene, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2029
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	10 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
VANILLIN (UNII: CH1530446X)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)	
CAPRYLIC/CAPRIC MONO/DI-GLYCERIDES (UNII: U72Q2I8C85)	
ALCOHOL (UNII: 3K9958V90M)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
ALOE VERA WHOLE (UNII: KIZ4X2EHYX)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SOYBEAN OIL (UNII: 241ATL177A)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
BEHENYL BEHENATE (UNII: K8NU647RJ0)	
SODIUM STEAROYL LACTYLATE (UNII: IN99IT31LN)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
ORANGE PEEL (UNII: T19T76XD44)	
.ALPHA.-TERPINYL ACETATE, (+)- (UNII: T3M2S9HES8)	
DIMETHYLHYDROXY FURANONE (UNII: 20PI8YZP7A)	
STARCH, POTATO (UNII: 8I089SAH3T)	
C9-11 ALKANE/CYCLOALKANE (UNII: 3EZ541F5MW)	
HEXASODIUM PHYTATE (UNII: ZBX50UG81V)	
NONANAL (UNII: 2L2WBY9K6T)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2029-1	59 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	
2	NDC:61995-2029-2	89 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	
3	NDC:61995-2029-3	113 g in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/19/2019	

Labeler - The Hain Celestial Group, Inc (117115556)**Registrant** - The Hain Celestial Group, Inc (014334364)**Establishment**

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc		081512382	manufacture(61995-2029)

Revised: 2/2023

The Hain Celestial Group, Inc