

AL00378 ALBA COOL SPORT SUNSCREEN SPF50- avobenzone, homosalate, octocrylene, octyl salicylate 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 Cool Sport SPF 50 Sunscreen

Avobenzone 3.0%

Homosalate 15.0%

Octocrylene 8.0%

Octyl Salicylate 5.0%

Sunscreen

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

For external use only. **Flammable.** Do not use near heat, sparks or flames or while smoking. Do not puncture or incinerate. Contents under pressure. Do not store at temperature above 120°C. Do not use on damaged or broken skin. When using this product keep out of eye. 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. Hold 4 to 6 inches away from body when spraying. Do not spray directly on face and avoid breathing mist. Spray on hand and apply to face. Use in well-ventilated areas. Reapply after 80 min of swimming or sweating, immediately after towel drying and at least every two hrs. Children under 6 months: 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.

Alcohol, Acrylates/Octylacrylamide Copolymer, Persea Gratissima (Avocado) Oil, Diisopropyl Adipate, Citrus Limon (lemon) Oil, Aloe Barbadensis Leaf Juice, Amyris Balsamifera Bark Oil, Camellia Sinensis Leaf Extract, Chamomilla Recuitita (Matricaria) Flower Extract, Panax Ginseng Root Extract, Ginkgo Biloba Root Extract, Tocopheryl Acetate, Triethyl Citrate, Benzyl Salicylate, Citral, Citronellol, Hexyl Cinnamal, Hydroxycitronellol, Limonene.

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

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PHOTO POLYMER PLATE

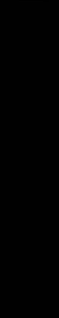
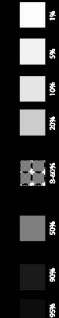
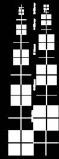


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avobenzone, homosalate, octocrylene, octyl salicylate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61995-2378
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8 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
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CHAMOMILE (UNII: FGL3685T2X)	

TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
GINKGO (UNII: 19FUJ2C58T)
ASIAN GINSENG (UNII: CUQ3A77YXI)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
ALCOHOL (UNII: 3K9958V90M)
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)
LIMONENE, (+)- (UNII: GFD7C86Q1W)
AMYRIS BALSAMIFERA OIL (UNII: IIBJ961J2E)
LEMON OIL (UNII: I9GRO824LL)
AVOCADO OIL (UNII: 6VNO72PFC1)
PEPPERMINT OIL (UNII: AV092KU4JH)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2378-6	177 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/14/2016	

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(61995-2378)