

**ALBA VE FACIAL SUNSCREEN SPF30- homosalate, octisalate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane, titanium dioxide 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.*

-----

**Active Ingredient**

**Homosalate - 7.5%**

**Octocrylene - 7.5%**

**Ethylhexyl Salicylate - 5.0%**

**Butyl Methoxydibenzoylmethane - 3.0%**

**Titanium Dioxide - 1.0%**

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, Glycerin, Glyceryl Stearate SE, Cetyl Alcohol, Dimethicone, Cetearyl Alcohol, VP/Hexadecene Copolymer, Caprylic/Capric Triglyceride, Hydrogenated Palm Cernel Oil, Aloe Barbadensis Leaf Juice(1), Camellia Sinensis Leaf Extract (1), Chamomilla Recutita (Matricaria) Flower Extract (1), Calendula Officinalis Flower Extract (1), Myrtus Communis Leaf Extract, Ginkgo Biloba Leaf Extract, Panax Ginseng Root Extract, Vitis Vinifera (Grape) Seed Extract, Cetearyl Alcohol, Cetearyl Oliviate, Polysorbate 60, Lecithin, Silica, Sodium Chloride, Sodium Stearoyl Glutamate, Sorbitan Oliviate, Tocopheryl Acetat, Xanthan Gum, Alcohol (1), Benzyl Alcohol, Ethylhexylglycerin, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate.

(1) Certified Organicf Ingredient

Helps prevents 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.



**ALBA VE FACIAL SUNSCREEN SPF30**

homosalate, octisalate, ethylhexyl salicylate, octocrylene, butyl methoxydibenzoylmethane, titanium dioxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61995-2095
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	7.5 g in 100 g
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
VITIS VINIFERA SEED (UNII: C34U15ICXA)	
MYRTUS COMMUNIS LEAF (UNII: U20N87188F)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALCOHOL (UNII: 3K9958 V90M)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
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)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CHAMOMILE (UNII: FGL3685T2X)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
HYDROGENATED PALM KERNEL OIL (UNII: FM8D1RE2VP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
GINKGO (UNII: 19FUJ2C58T)	
ASIAN GINSENG (UNII: CUQ3A77YXI)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-2095-4	113 g in 1 TUBE; Type 0: Not a Combination Product	10/15/2013	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/15/2013	

**Labeler** - The Hain Celestial Group, Inc. (858894996)

**Registrant** - The Hain Celestial Group, Inc. (858894996)

**Establishment**

Name	Address	ID/FEI	Business Operations
The Hain Celestial Group, Inc.		858894996	manufacture(61995-2095)

Revised: 11/2014

The Hain Celestial Group, Inc.