

**AV3630000 AVALON ORGANICS ECZEMA RELIEF INTENSIVE- colloidal oatmeal cream**

**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.*

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**AV3630000 Avalon Organics Eczema Relief Intensive**

**Active Ingredient**

**Colloidal Oatmeal - 1.5%**

Instantly soothe and protect skin by smoothing over areas of intense irritation.

Skin Protectant

For external use only. Avoid contacts with eyes. Stop use and ask a doctor if symptoms last more than 7 days or condition worsens.

Keep out of reach of children. If swallowed get medical help or contact Poison Center immediately.

Aloe Barbadensis Leaf Juice (1)

Carthamus Tinctorius (Safflower) Seed Oil (1)

Cocos Nucifera (Coconut) Oil (1)

Glycerin

Cetearyl Olivatate

Shea Butter Ethyl Esters

Sorbitan Olivatate

Glyceryl Stearate SE

Aqua (Purified Water)

Butyrospermum Parkii (Shea) Butter (1)

Linum Usitatissimum (Linseed) Seed Oil (1)

C10-18 Triglycerides

Gluconolactone

Behenyl Alcohol

Archidyl Alcohol

Arginine

Biosaccharide gum-1

Calcium Gluconate

Glyceryl Caprylate

Sodium Anisate

Sodium Levulinate

Stearyl Alcohol

Potassium Sorbate

Sodium Benzoate

(1) Certified Organic Ingredient

Helps protect and relieve skin irritation and itching due to: Eczema, Rashes, Dry skin.



## AV3630000 AVALON ORGANICS ECZEMA RELIEF INTENSIVE

colloidal oatmeal cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61995-1300
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	1.5 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>ARGININE</b> (UNII: 94ZLA3W45F)	
<b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	
<b>LINSEED OIL</b> (UNII: 84XB4DV00W)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>SODIUM LEVULINATE</b> (UNII: VK44E1MQU8)	
<b>GLYCERYL CAPRYLATE</b> (UNII: TM2TZD4G4A)	
<b>C10-18 TRIGLYCERIDES</b> (UNII: 43AGM4PHPI)	
<b>SODIUM ANISATE</b> (UNII: F9WFJ28MV9)	
<b>SHEA BUTTER ETHYL ESTERS</b> (UNII: V2CI786FPG)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61995-1300-3	89 g in 1 TUBE; Type 0: Not a Combination Product	02/08/2017	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/08/2017	

**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(61995-1300)

Revised: 4/2021

The Hain Celestial Group, Inc.