

AL0040600 ALBA COOLING ALOE BURN RELIEF- menthol, allantoin 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 Botanica Cooling Aloe Burn Relief Spray

Allantoin 0.5%

Menthol 0.5%

Mentol - Topical Analgetic

Allantoin - Skin Protectant

- Provides cooling pain relieve
- Skin protection and first aid for the temporary relief of pain and itching associated with sunburn, minor burns, minor skin irritations, insect bites, minor cuts and scrapes

For external use only. Avoid contact with eyes, mouth and mucous membranes. Do not use on deep puncture wounds, animal bites or serious burns. Do not puncture or incinerate. Contents under pressure .Do not store at temperature above 120°. 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 doctor** if condition worsens, lasts more than 7days or clears up and occurs again in within a few days or if skin rash occurs.

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

Adults and children 2 years old and older: apply to affected area up to 4 times daily or as directed by doctor. Hold 4-6 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-ventiled area. **Children under 2 years of age :** ask a doctor.

Aquq (Water),Glycerin, Caprylyl/Capric Glucoside, Aloe Barbadensis Leaf Juice, Cananga Odarata Flower Oil, Mentha Piperita (Peppermint) Oil, Cucumis Sativus (Cucumber) Fruit Extract, Calendula Officinalis Flower Extract, Camellia Sinensis Leaf Extract, Pyrus Malus (Apple) Fruit Extract, Caprylic/Capric Triglyceride, Citric Acid, Terpeneol, Phenoxyethanol, Potassium Sorbate, Sodium Benzoate, Hexyl Cinnamal, Hydroxycitronellol, Limonene, Linalool.

Questions? Visit www.albobotanica.com or call 888-659-7730



AL0040600 ALBA COOLING ALOE BURN RELIEF

menthol, allantoin spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61995-2406 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z) | ALLANTOIN | 0.5 g in 100 g |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 0.5 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CANANGA OIL (UNII: 8YOY78GNNX) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |

| |
|---|
| APPLE (UNII: B423VGH5S9) |
| WATER (UNII: 059QF0KO0R) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0) |
| LAVENDER OIL (UNII: ZBP1YXW0H8) |
| CUCUMBER (UNII: YY7C30VXJT) |
| TERPINEOL (UNII: R53Q4ZWC99) |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |
| HYDROXYCITRONELLOL (UNII: R0B4U2I48W) |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) |
| PEPPERMINT OIL (UNII: AV092KU4JH) |
| SODIUM BENZOATE (UNII: OJ245FE5EU) |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61995-2406-6 | 177 g in 1 CAN; Type 0: Not a Combination Product | 01/13/2016 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347 | 01/13/2016 | |

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 | | 117115556 | manufacture(61995-2406) |

Revised: 10/2019

The Hain Celestial Group, Inc