

AL0038400 ALBA BOTANICA FAST FIX SUN SPF30- octocrylene, octyl salicylate, zinc oxide stick

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 Fast Fix Sun Stick SPF 30

Active Ingredient

Octyl Salicylate - 5.0 %

Octocrylene - 10.0 %

Zinc Oxide - 20.0 %

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. Children under 6 months: ask a doctor.

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.

Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil (1), Euphorbia Cerifera (Candelilla) Wax, Jojoba Esters, Glycerin, Hydrogenated Glyceryl Abietate, Glyceryl Behenate, Copernicia Cerifera (Carnauba) Wax, Cetearyl Alcohol, Raphanus Sativus (Radish) Seed Oil, Aloe Barbadensis Leaf Juice(1), Chamomilla Recutita (Matricaria) Flower Extract (1), Butyrospermum Parkii (Shea) Butter (1), Polysorbate 60, Tocopheryl, Theobroma Cacao (Cocoa) Seed Butter (1), Punica Granatum Seed Oil (1), Helianthus Annuus (Sunflower) Seed Oil, Natural Flavor, Citrus Aurantifolia (Lime) Oil, Euterpe Oleracea Fruit Extract (1), Panax Ginseng Root Extract.

(1) Certified Organic Ingredient

Helps prevent 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.



new


alba[®]
BOTANICA[™]



fast
fix^{sun}
stick

spf 30
broad spectrum

water resistant (80 minutes)
reef safe

 no oxybenzone, octinoxate
or synthetic fragrances
100% vegetarian ingredients

Net Wt 14 g e 0.5 oz



**hands-free, mess-free, carefree
protection glides right on**

- Use for face and body protection or for quick touch-ups throughout your day
- Great for "hot spots" like cheeks, ears and noses
- Loved by moms, dads AND kids for durable, easy-to-apply, stay-put protection

Drug Facts

Active Ingredient

| | |
|----------------------------|-----------|
| Octocrylene 10.0%..... | Sunscreen |
| Octyl Salicylate 5.0%..... | Sunscreen |
| Zinc Oxide 20.0%..... | Sunscreen |

Purpose

Uses • Helps prevent sunburn • If used as directed with other sun protection measures (see **Directions**), decreases risk of skin cancer and early skin aging caused by 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 and 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 10am to 2pm, and • wear long-sleeved shirts, pants, hats and sunglasses.

Inactive Ingredients Caprylic/Capric Triglyceride, Cocos Nucifera (Coconut) Oil⁽¹⁾, Euphorbia Cerifera (Candelilla) Wax, Jojoba Esters, Glycerin, Hydrogenated Glyceryl Abietate, Glyceryl Behenate, Copernicia Cerifera (Carnauba) Wax, Raphanus Sativus (Radish) Seed Oil, Cetearyl Alcohol, Polysorbate 60, Natural Flavor, Butyrospermum Parkii (Shea) Butter⁽¹⁾, Theobroma Cacao (Cocoa) Seed Butter⁽¹⁾, Helianthus Annuus (Sunflower) Seed Oil, Punica Granatum Seed Oil⁽¹⁾, Aloe Barbadensis Leaf Juice⁽¹⁾, Chamomilla Recutita (Matricaria) Flower Extract, Citrus Aurantifolia (Lime) Oil, Euterpe Oleracea Fruit Extract⁽¹⁾, Panax Ginseng Root Extract, Tocopherol, Limonene ⁽¹⁾**Certified Organic Ingredient**

Other Information Protect this product from excessive heat and direct sun

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

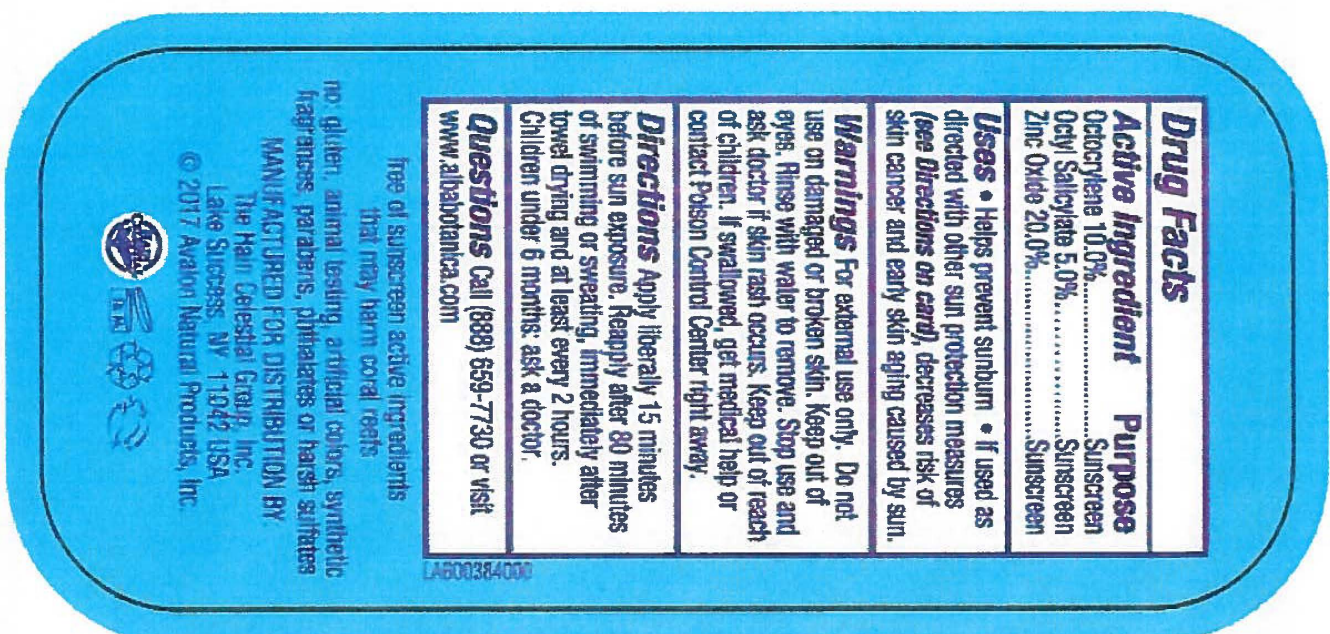
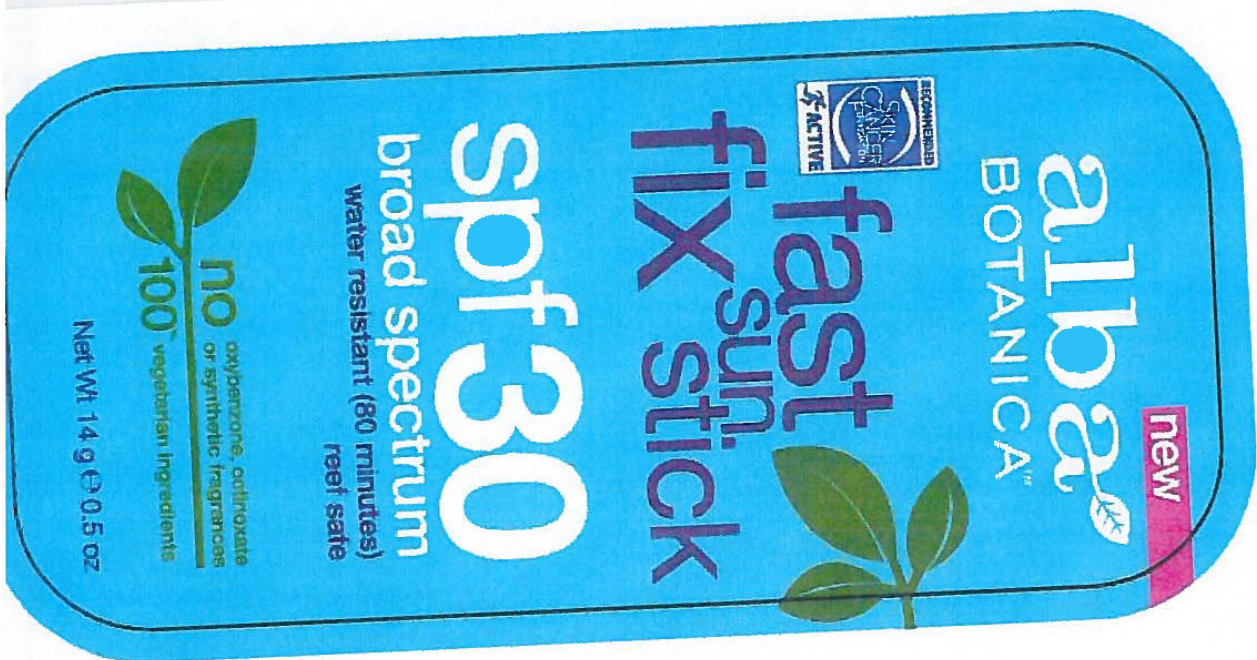
free of sunscreen active ingredients that may harm coral reefs

100% vegetarian ingredients.

no: gluten, animal testing, artificial colors, synthetic fragrances, parabens, phthalates, or harsh sulfates.

MANUFACTURED FOR DISTRIBUTION BY:
The Hain Celestial Group, Inc.
Lake Success, NY 11042 USA
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CARD00384000





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|--|------------------|--|----------------------|--------------------|
| octocrylene, octyl salicylate, zinc oxide stick | | | | |
| | | | | |
| Product Information | | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61995-2384 | |
| Route of Administration | TOPICAL | | | |
| | | | | |
| Active Ingredient/Active Moiety | | | | |
| Ingredient Name | | Basis of Strength | Strength | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | | ZINC OXIDE | 20 g in 100 g | |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | | OCTISALATE | 5 g in 100 g | |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | | OCTOCRYLENE | 10 g in 100 g | |
| | | | | |
| Inactive Ingredients | | | | |
| Ingredient Name | | | Strength | |
| TOCOPHEROL (UNII: R0ZB2556P8) | | | | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | |
| SHEA BUTTER (UNII: K49155WL9Y) | | | | |
| CHAMOMILE (UNII: FGL3685T2X) | | | | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | | | | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | | | | |
| GLYCERYL MONOBEHENATE (UNII: A626UU0W2A) | | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | |
| COCOA BUTTER (UNII: 512OYT1CRR) | | | | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | | | | |
| PUNICA GRANATUM SEED OIL (UNII: 0UI45XV0T6) | | | | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | | | | |
| COCONUT OIL (UNII: Q9L0O73W7L) | | | | |
| CANDELILLA WAX (UNII: WL0328HX19) | | | | |
| GLYCERYL ABIETATE (UNII: 2F22LY70Q1) | | | | |
| HYDROGENATED JOJOBA OIL, RANDOMIZED (UNII: Q47ST02F58) | | | | |
| RAPHANUS SATIVUS VAR. SATIVUS SEED (UNII: A94I086Q5E) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:61995-2384-1 | 1 in 1 CARTON | 12/26/2017 | |
| 1 | | 14 g in 1 CONTAINER; Type 0: Not a Combination Product | | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | | part352 | 12/26/2017 | |

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(61995-2384) |

Revised: 2/2021

The Hain Celestial Group, Inc.