

H.E.B SOLUTIONS SUNSCREEN- ultra spf 70 continuous spray aerosol, spray
H.E.B

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.

H.E.B Solutions Sunscreen Ultra SPF 70 Continuous Spray

Active ingredients

Avobenzone 3.0%, Homosalate 15.0%, Octisalate 5.0%, Octocrylene 10.0%, Oxybenzone 6.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

FLAMMABLE:

- do not use near heat, flame or while smoking
- avoid long term storage above 104°F (40°C)

Do not use • on damaged or broken skin.

When using this product • keep out of eyes. Rinse with water to remove. • do not puncture or incinerate. Contents under pressure. • do not store at temperatures above 120°F.

Stop use and ask a doctor if • 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
- hold can 4-6 inches away from body, spray evenly to ensure complete coverage
- do not spray into face. Spray into hand and apply to face.
- use in well ventilated, but not windy areas
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
 - children under 6 months of age: ask a doctor

- **☀Sun Protection Measures☀**. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. - 2 p.m.
 - wear long-sleeve shirts, pants, hats, and sunglasses

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

Inactive ingredients

SD alcohol 40-B, acrylates/octylacrylamide copolymer, aloe barbadensis leaf juice, tocopherol, camellia sinensis leaf extract (green tea), chamomilla recutita (matricaria) flower extract, glycerin, saccharomyces/podophyllum peltatum ferment filtrate, stearoxytrimethylsilane, caprylic/capric triglyceride, fragrance, butylene glycol, propylene glycol

Questions or Comments?

Call toll free 1-800-527-7731

H.E.B Solutions Sunscreen Ultra SPF 70 Continuous Spray

5.5 OZ (156g)

NDC 37808-975-37

Dermatologist tested
 Oil Free • PABA Free • Rub-Free Formula
 Hypoallergenic
 Contains Aloe, Chamomile Extract,
 and Green Tea Extract

Drug Facts

| Active Ingredients | Purpose |
|--|-----------|
| Avobenzone 3% Homosalate 15% Octisalate 5% Octocrylene 10% Oxybenzone 6% | Sunscreen |

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MADE WITH PRIDE
 AND CARE FOR H-E-B®,
 SAN ANTONIO, TEXAS 78204

PLEASE RECYCLE



SOLUTIONS™
 SUNSCREEN

ULTRA 70
 Ultra
 Sunscreen
 UVA/UVB Protection
 Water Resistant
 (80 minutes)
 Paraben Free

BROAD SPECTRUM SPF 70



NET WT. 5.5 OZ (156 g)

H.E.B SOLUTIONS SUNSCREEN

ultra spf 70 continuous spray aerosol, spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:37808-975 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 g |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 150 mg in 1 g |

| | | |
|---|-------------|---------------|
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 50 mg in 1 g |
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 100 mg in 1 g |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 60 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALCOHOL (UNII: 3K9958V90M) | |
| ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8VWK) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:37808-975-37 | 156 g in 1 CAN; Type 0: Not a Combination Product | 02/17/2012 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 02/17/2012 | |

Labeler - H.E.B (007924756)

Registrant - Fruit of the Earth, Inc. (079559467)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--------------------------|---------|-----------|------------------------|
| Fruit of the Earth, Inc. | | 008193513 | manufacture(37808-975) |