

## **H.E.B ULTRA- spf 30 sunscreen 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.*

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## **H-E-B SOLUTIONS SUNSCREEN ULTRA SPF 30 CONTINUOUS SPRAY**

### ***Active Ingredients***

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 2.0%

### ***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.

**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 Ingredient(s)***

SD alcohol 40-B, butyloctyl salicylate, acrylates/octylacrylamide copolymer, glycerin, caprylic/capric triglyceride, stearoxytrimethylsilane, tocopherol, butylene glycol, panthenol, saccharomyces/podophyllum peltatum ferment filtrate

***Questions or Comments?***

Call toll free 1-800-527-7731

H-E-B SOLUTIONS SUNSCREEN ULTRA SPF 30 CONTINUOUS SPRAY

5.5 OZ (156g)

NDC 37808-923-37

Dermatologist Tested · Hypoallergenic  
Oil Free · PABA Free  
Retinyl Palmitate Free · Fragrance Free  
Contains Vitamin B5 and Vitamin E

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2%	Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> For external use only	
<b>FLAMMABLE:</b> • do not use near heat, flame or while smoking • avoid long term storage above 104°F (40°C)	
<b>Do not use</b> • on damaged or broken skin.	
<b>When using this product</b> • 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.	
<b>Stop use and ask a doctor if</b> • rash occurs.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
• 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 • <b>Sun Protection Measures.</b> 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	
<b>Other Information</b> • protect this product from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces	
<b>Inactive Ingredients</b> SD alcohol 40-B, butylacetyl salicylate, acrylates/octylacrylamide copolymer, glycerin, caprylic/capric triglyceride, stearoxytrimethylsilane, tocopherol, butylene glycol, panthenol, saccharomyces/podophyllum peltatum ferment filtrate	
<b>Questions or Comments?</b> Call toll free 1-800-527-7731	

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



**ULTRA 30**  
**ULTRA 30**  
**ULTRA 30**

**OXYBENZONE FREE**

**Ultra Sunscreen**

UVA/UVB Protection  
Water Resistant  
(80 minutes)  
Paraben Free

**BROAD SPECTRUM SPF 30**



NET WT. 5.5 OZ (156 g)

**H.E.B ULTRA**

spf 30 sunscreen aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-924
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	100 mg in 1 g

<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW)</b> (UNII: JU3XHR8VWK)	
<b>PANTHENOL</b> (UNII: WV9CM0O67Z)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>STEAROXYTRIMETHYLSILANE</b> (UNII: 9862TW94B2)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-924-37	156 g in 1 CAN; Type 0: Not a Combination Product	04/24/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/24/2019	

**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(37808-924)