

## **H.E.B ULTRA- spf 50 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 50 LOTION**

### ***Active Ingredients***

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 4.5%, Octocrylene 8.0%

### ***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**

**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
- 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)***

water, glycerin, silica, aluminum starch octenylsuccinate, behenyl alcohol, phenoxyethanol, glyceryl stearate, arachidyl alcohol, ethylhexylglycerin, arachidyl glucoside, PEG-100 stearate, sodium ascorbyl phosphate, saccharomyces/podophyllum peltatum ferment filtrate, polyester-7, neopentyl glycol diheptanoate, styrene/acrylates copolymer, isododecane, tocopherol (vitamin E), beeswax, potassium hydroxide, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, butylene glycol

***Questions or Comments?***

Call toll free 1-800-527-7731

H-E-B SOLUTIONS SUNSCREEN ULTRA SPF 50 LOTION

8 FL OZ (237mL)

NDC 37808-914-12



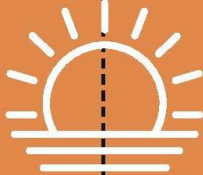
# SOLUTIONS™ SUNSCREEN

# ULTRA 50

Oxybenzone  
Free Sunscreen

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

BROAD SPECTRUM SPF 50



8 FL OZ (237 mL)

Dermatologist Tested  
Oil Free • PABA Free  
Retinyl Palmitate Free • Fragrance Free  
Hypoallergenic  
Contains Vitamin E

### Drug Facts

Active Ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 4.5% Octocrylene 8%	Sunscreen

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• limit time in the sun, especially from 10am-2pm  
• 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)**  
water, polyester-7, neopentyl glycol diheptanoate, glycerin, styrene/acrylates copolymer, aluminum starch octenylsuccinate, saccharomyces/podophyllum peltatum ferment filtrate, butylene glycol, silica, phenoxyethanol, isododecane, arachidyl alcohol, beeswax, ethylhexylglycerin, acrylates/C10-30 alkyl acrylate crosspolymer, behenyl alcohol, tocopherol (vitamin E), arachidyl glucoside, glyceryl stearate, PEG-100 stearate, potassium hydroxide, disodium EDTA, sodium ascorbyl phosphate.

**Questions or Comments?** Call toll free 1-800-527-7731

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



9569-1811



## H.E.B ULTRA

spf 50 sunscreen aerosol, spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-914
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 mL

<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	45 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	80 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ0O6294)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35JOOJ)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>POLYESTER-7</b> (UNII: 0841698D2F)	
<b>NEOPENTYL GLYCOL DIHEPTANOATE</b> (UNII: 5LKW3C543X)	
<b>ISODODECANE</b> (UNII: A8289P68Y2)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>BUTYLENE GLYCOL</b> (UNII: 3XUS85K0RA)	
<b>YELLOW WAX</b> (UNII: 2ZA36H0S2V)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-914-12	237 mL in 1 TUBE; Type 0: Not a Combination Product	02/05/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part352	02/05/2019	

**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(37808-914)

