# H.E.B- 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 CONTINUOUS SPRAY

## **Active Ingredients**

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 5.0%, Octocrylene 4.0%

## **Purpose**

Sunscreen

### Uses

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

## Warnings

**IFor external use only** 

## **FLAMMABLE:**

- do not use near heat, flame or while smoking
- avoid long term stoage 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.
- wearl 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, butyloctyl salicylate, acrylates/octylacrylamide copolymer, glycerin, saccharomyces/podophyllum peltatum ferment filtrate, caprylic/capric triglyceride, stearoxytrimethylsilane, tocopherol, panthenol, butylene glycol

## **Questions or Comments?**

Call toll free 1-800-527-7731 H-E-B SOLUTIONS SUNSCREEN ULTRA SPF 50 CONTINUOUS SPRAY 5.5 OZ (156g)

NDC 37808-996-37

Oil Free • PABA Free Retinyl Palmitate Free • Fragrance Free Contains Vitamin B5 and Vitamin E

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











Oxybenzone Free Sunscreen

**UVA/UVB Protection** Water Resistant (80 minutes)

Paraben Free

**BROAD SPECTRUM SPF 50** 





NET WT. 5.5 OZ (156 g)

## H.E.B

spf 50 sunscreen aerosol, spray

## **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-996
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Route of Administration TOPICAL

## Active Ingredient/Active Meietr

Active ingredient/Active Molety				
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		

l	OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 g
l	OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ACRYLATE/ISOBUTYL METHACRYLATE/N-TERT-OCTYLACRYLAMIDE COPOLYMER (75000 MW) (UNII: JU3XHR8 VWK)	
TOCOPHEROL (UNII: R0 ZB2556 P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEARO XYTRIMETHYLSILANE (UNII: 9862TW94B2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)	
PANTHENOL (UNII: WV9CM0O67Z)	

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1 NDC:37808-996-37	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	0 4/24/20 19		

# **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(37808-996)	

Revised: 3/2020 H.E.B