

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.

H-E-B SOLUTIONS SUNSCREEN BANANA 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 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, butyloctyl salicylate, acrylates/octylacrylamide copolymer, glycerin, saccharomyces/podophyllum peltatum ferment filtrate, caprylic/capric triglyceride, stearoxytrimethylsilane, tocopherol, panthenol, butylene glycol, fragrance

Questions or Comments?

Call toll free 1-800-527-7731

H-E-B SOLUTIONS SUNSCREEN BANANA SPF 50 CONTINUOUS SPRAY

5.5 OZ (156g)

NDC 37808-912-37



H.E.B			
spf 50 sunscreen aerosol, spray			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-912
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
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
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: JU3XHR8VWK)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
STEAROXYTRIMETHYLSILANE (UNII: 9862TW94B2)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
PANTHENOL (UNII: WV9CM0O67Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-912-37	156 g in 1 CAN; Type 0: Not a Combination Product	03/07/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/07/2019	

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(37808-912)

Revised: 3/2020

H.E.B