

H.E.B SOLUTIONS SUNSCREEN- ultra spf 50 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 50 Continuous Spray

☐Active ingredients

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

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, cyclopentasiloxane, octyldodecyl citrate crosspolymer, trimethylpentanediol/adipic acid/ glycerin crosspolymer, ethyl methicone, bis-hydroxyethoxypropyl dimethicone, acrylates/dimethicone copolymer, fragrance, tocopheryl acetate, nelumbo nucifera flower extract, ascorbyl palmitate, propylene 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 37808-965-37

Dermatologist tested
 Oil Free • PABA Free • Rub-Free Formula
 Hypoallergenic
 Contains Vitamin E, Vitamin C,
 and Lotus Extract

Drug Facts	
Active ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 10% Oxybenzone 6%	Sunscreen
Uses • 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	
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.	
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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, cyclopentasiloxane, octyldodecyl citrate crosspolymer, trimethylpentanediol/adipic acid/glycerin crosspolymer, ethyl methicone, bis-hydroxyethoxypropyl dimethicone, acrylates/dimethicone copolymer, fragrances, tocopheryl acetate, nelumbo nucifera flower extract, ascorbyl palmitate, propylene glycol	
Questions or comments? Call toll free 1-800-527-7731	

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



SOLUTIONS™
 SUNSCREEN

ULTRA 50

**WET PROTECTION
 Sunscreen**

UVA/UVB Protection
 Sweat and Water
 Resistant (80 minutes)
 Paraben Free
 Protects Wet or
 Dry Skin

BROAD SPECTRUM SPF 50



NET WT. 5.5 OZ (156 g)

H.E.B SOLUTIONS SUNSCREEN

ultra spf 50 continuous spray aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-965
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	100 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
TRIMETHYLPENTANEDIOL/ADIPIC ACID/GLYCERIN CROSSPOLYMER (25000 MPA.S) (UNII: 587WKM3S9Q)	
ETHYL METHICONE (8 MPA.S) (UNII: 3YWG8XYT8H)	
BIS-HYDROXYETHOXYPROPYL DIMETHICONE (50 CST) (UNII: YP714N2H05)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
NELUMBO NUCIFERA FLOWER (UNII: 61W322NLDV)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-965-37	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(37808-965)

Revised: 3/2020

H.E.B