

## **H.E.B SOLUTIONS SUNSCREEN- kids spf 50 lotion 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 Kids SPF 50 Lotion Spray**

### **☐Active ingredients**

Avobenzone 3.0%, Homosalate 13.0%, Octisalate 5.0%, Octocrylene 2.0%, Oxybenzone 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**

☐**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***

water, sorbitol, VP/eicosene copolymer, stearic acid, styrene/acrylates copolymer, aloe barbadensis leaf juice, triethanolamine, sorbitan isostearate, chamomilla recutita (matricaria) flower extract, propylene glycol, benzyl alcohol, dimethicone, tocopherol (vitamin E), polyglyceryl-3 distearate, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, phenoxyethanol, capryloyl glycine, undecylenoyl glycine

***Questions or comments?***

Call toll free 1-800-527-7731

H.E.B Solutions Sunscreen Kids SPF 50 Lotion Spray

6.3 OZ (178g)

NDC 37808-983-50

Dermatologist Tested  
 Oil Free • PABA Free  
 Hypoallergenic  
 Contains Aloe, Chamomile Extract  
 and Vitamin E

<b>Drug Facts</b>	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3% Homosalate 13% Octisalate 5% Octocrylene 2% Oxybenzone 4%	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>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.	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>• apply liberally 15 minutes before sun exposure</li> <li>• hold can 4-6 inches away from body, spray evenly to ensure complete coverage</li> <li>• do not spray into face. Spray into hand and apply to face.</li> <li>• use in well ventilated, but not windy areas</li> <li>• reapply:               <ul style="list-style-type: none"> <li>• after 80 minutes of swimming or sweating</li> <li>• immediately after towel drying</li> <li>• at least every 2 hours</li> </ul> </li> <li>• children under 6 months of age: ask a doctor</li> <li>• <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:               <ul style="list-style-type: none"> <li>• limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>• wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>• protect this product from excessive heat and direct sun</li> <li>• may stain or damage some fabrics, materials or surfaces</li> </ul>	
<b>Inactive ingredients</b>	
water, sorbitol, VP/eicosene copolymer, stearic acid, styrene/acrylates copolymer, aloe barbadensis leaf juice, triethanolamine, sorbitan laurate, chamomilla recutita (matricaria) flower extract, propylene glycol, benzyl alcohol, dimethicone, tocopherol (vitamin E), polyglyceryl-3 distearate, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, phenoxyethanol, capryloyl glycine, undecylenoyl glycine	
<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



SOLUTIONS™  
 SUNSCREEN

**KID 50**  
**LOTION SPRAY**  
**Sunscreen**

UVA/UVB Protection  
 Sweat and Water  
 Resistant (80 minutes)  
 Paraben Free  
 Sprays white to  
 ensure coverage

**BROAD SPECTRUM SPF 50**



NET WT 6.3 OZ (178 g)

H.E.B Solutions Sunscreen Kids SPF 50 Lotion Spray Twin Pack

(2x) 6.3 OZ (178g)

NDC 37808-983-76

**APPROVED**

By Nicollette Sherrod at 4:46 pm, Dec 19, 2018

Dermatologist Tested  
Oil Free · PABA Free · Hypoallergenic  
Contains Aloe, Chamomile Extract  
and Vitamin E



**H.E.B.**  
SOLUTIONS™  
SUNSCREEN



**KIDS  
50**

LOTION SPRAY Sunscreen

UVA/UVB Protection  
Sweat and Water Resistant (80 minutes)  
Paraben Free  
Sprays white to ensure coverage  
**BROAD SPECTRUM SPF 50**



Drug Facts	Purpose
<b>Active Ingredients</b> Avobenzone 3% Homosalate 13% Octisalate 5% Octocrylene 2% Oxybenzone 1%	Sunscreen
<b>Uses</b> • 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	
<b>Warnings</b> 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. • do not puncture or scratch. 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.	
<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 • 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	
<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> water, sorbitol, Polyoxane copolymer, stearic acid, diethylene glycol copolymer, also butadiene, leaf juice, hydroxylamine, acrylate, octadecyl, chamomile methyl methacrylate, shear extract, propylene glycol, benzyl alcohol, dimethicone, tocopherol, vitamin E, polypropylene glycol, acrylates/C10-30 alkyl acrylate crosspolymer, disodium EDTA, phenylethyl alcohol, glycerin, xanthan gum	
<b>Questions or Comments?</b> Call toll free 1-800-922-7721	

MADE WITH PRIDE AND CARE FOR US • SAN ANTONIO, TEXAS 78204

## H.E.B SOLUTIONS SUNSCREEN

kids spf 50 lotion spray aerosol, spray

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-983
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	130 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	40 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
EICOSYL POVIDONE (UNII: XQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
PHENOXYETHANOL (UNII: H1E492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TOCOPHEROL (UNII: R0ZB2556P8)	

<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CHAMOMILE</b> (UNII: FGL3685T2X)	
<b>CARBOMER COPOLYMER TYPE A</b> (UNII: 71DD5V995L)	

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-983-76	2 in 1 PACKAGE	03/04/2017	
1	NDC:37808-983-50	156 g in 1 CAN; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/09/2012	

**Labeler** - H.E.B (007924756)

**Registrant** - Fruit of the Earth, Inc. (079559467)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Fruit of the Earth, Inc.		008193513	manufacture(37808-983)