

H.E.B SOLUTIONS SUNSCREEN- baby 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 Baby 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 Baby SPF 50 Lotion Spray

6.3 OZ (178g)

NDC 37808-984-50

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

Drug Facts	
Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 13%	
Octisalate 5%	
Octocrylene 2%	
Oxybenzone 4%	
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	
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	
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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

BABY 50
LOTION SPRAY
Baby Sunscreen

UVA/UVB Protection
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

baby spf 50 lotion spray aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-984
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: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
EICOSYL POVIDONE (UNII: XQQ9MKE2BJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLOYL GLYCINE (UNII: 8TY5YO42NJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHAMOMILE (UNII: FGL3685T2X)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-984-50	178 g in 1 CAN; Type 0: Not a Combination Product	04/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/22/2019	

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(37808-984)