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

IFor 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 if1 • 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?

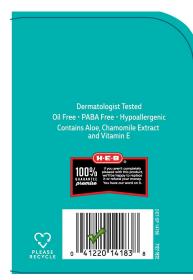
Call toll free 1-800-527-7731 H.E.B Solutions Sunscreen Kids SPF 50 Lotion Spray 6.3 OZ (178g) NDC 37808-983-50



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

(2x) 6.3 OZ (178g)

NDC 37808-983-76





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



2 - 6.3 OZ (178 g) CANS • NET WT. 12.6 OZ (356 g)

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





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: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 g	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	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: ZY8 1Z8 3H0 X)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470 XV)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
CAPRYLO YL GLYCINE (UNII: 8TY5YO42NJ)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
TOCOPHEROL (UNII: R0ZB2556P8)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CHAMO MILE (UNII: FGL3685T2X)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Packaging				
#	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		

Marketing Information			
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)

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

Revised: 3/2020 H.E.B