H.E.B SOLUTIONS SUNSCREEN- kids spf 70 lotion lotion 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 70 Lotion

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octisalate 3.0%, Octocrylene 7.0%, Oxybenzone 6.0%

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.

Stop use and ask a doctor if ● rash occurs

□Keep out of reach of children. □ If sproduct is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **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
- children under 6 months: ask a doctor

Inactive ingredients

water, propylene glycol, styrene/acrylates copolymer, silica, aluminum starch octenylsuccinate, behenyl

alcohol, butylated PVP, glyceryl stearate, microcrystalline cellulose, benzyl alcohol, diethylhexyl syringylidenemalonate, palmitic acid, myristyl alcohol, stearic acid, saccharomyces/podophyllum peltatum ferment filtrate, lauryl alcohol, cetyl alcohol, aloe barbadensis leaf juice, chamomilla recutita (matricaria) flower extract, tocopherol (vitamin E), lecithin, cellulose gum, chlorphenesin, disodium EDTA, butylene glycol

Other information

- protect this product from excessive heat and direct sun
- may stain or damage some fabrics, materials or surfaces

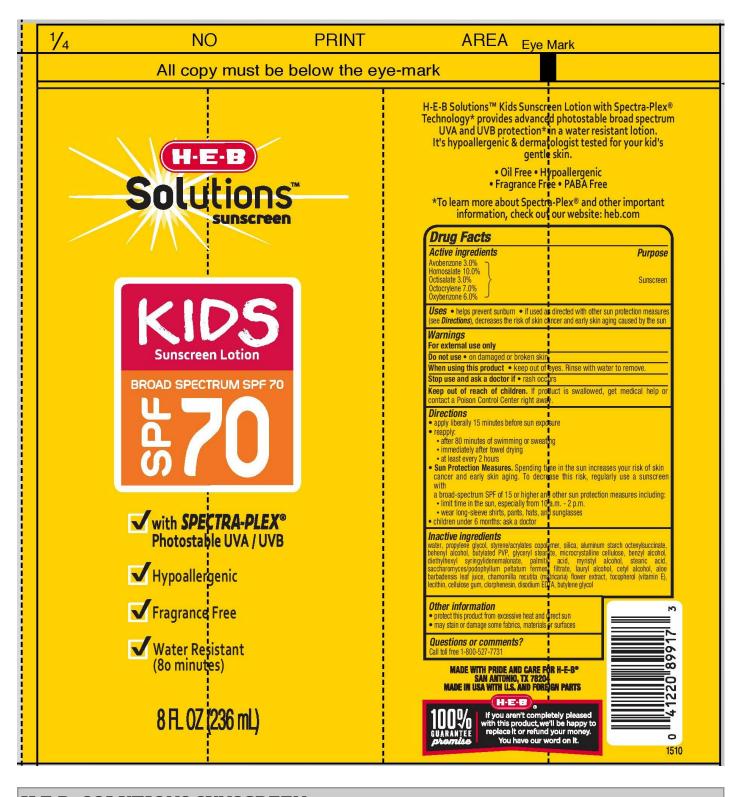
Questions of comments?

Call toll free 1-800-527-7731

H.E.B Solutions Sunscreen Kids SPF 70 Lotion

8 FL OZ (237mL)

NDC 37808-955-12



H.E.B SOLUTIONS SUNSCREEN

kids spf 70 lotion lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-955
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 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	30 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	70 mg in 1 mL
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ0O6294)	
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PALMITIC ACID (UNII: 2V16EO95H1)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LAURYL ALCOHOL (UNII: 178 A96 NLP2)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
CHAMO MILE (UNII: FGL3685T2X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LECITHIN, SO YBEAN (UNII: 1DI56QDM62)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679 OBS 311)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	

Packaging				
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:37808-955-12	237 mL in 1 TUBE; Type 0: Not a Combination Product	02/21/2012	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	0 2/21/20 12		

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(37808-955)	

Revised: 3/2020 H.E.B