

HEB- general protection spf 100 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.

HEB Solutions Sunscreen Ultra 100 Lotion

Active Ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%, Oxybenzone 6%

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.

☐**Stop use and ask 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
- 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 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, propylene glycol, styrene/acrylates copolymer, silica, aluminum starch octenylsuccinate, behenyl alcohol, glyceryl stearate, microcrystalline cellulose, benzyl alcohol, 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, butylated PVP, disodium EDTA, butylene glycol

HEB Solutions Sunscreen Ultra 100 Lotion

8 FL OZ (237)

NDC 37808-943-12

H-E-B
SOLUTIONSTM
SUNSCREEN

ULTRA 100

Ultra Sunscreen

UVA/UVB Protection
Water Resistant (80 minutes)
Paraben Free

BROAD SPECTRUM SPF 100

8 FL OZ (237 mL)

GO TEXAN[®]

Dermatologist Tested
Oil Free · PABA Free
Retinyl Palmitate Free · Fragrance Free
Hypoallergenic
Contains Aloe, Chamomile Extract, Vitamin E

Active Ingredients	Purpose
Avobenzene 3%	Sunscreen
Homosalate 15%	
Octisalate 5%	
Octocrylene 10%	
Oxybenzone 6%	

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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
• 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 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 10am-2pm
• 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 Ingredient(s)
water, propylene glycol, styrene/acrylates copolymer, silica, aluminum starch octenylsuccinate, behenyl alcohol, glyceryl stearate, microcrystalline cellulose, benzyl alcohol, 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, butylated PVP, disodium EDTA, butylene glycol.

Questions or Comments? Call toll free 1-800-527-7731

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

7127-1811

PLEASE RECYCLE

H-E-B
100% GUARANTEE promise
If you aren't completely pleased with this product, we'll be happy to replace it or refund your money. You have our word on it.

0 4 1220 89900 5

HEB

general protection spf 100 lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-943
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	150 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ0O6294)	
DOCOSANOL (UNII: 9G1OE216XY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PALMITIC ACID (UNII: 2V16EO95HI)	
MYRISTYL ALCOHOL (UNII: V42034O9PU)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LAURYL ALCOHOL (UNII: 178A96NLP2)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CHAMOMILE (UNII: FGL3685T2X)	
TOCOPHEROL (UNII: R0ZB2556P8)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CHLORPHENESIN (UNII: I670DAL4SZ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
N-VINYLPYRROLIDINONE (UNII: 76H9G81541)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-943-12	237 mL in 1 TUBE; Type 0: Not a Combination Product	11/12/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/12/2019	

Labeler - H-E-B (007924756)

Registrant - Fruit Of The Earth, Inc. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit Of The Earth Research Laboratories, Inc.		008193513	manufacture(37808-943)

Revised: 3/2020

H-E-B