

H.E.B SOLUTIONS SUNSCREEN- ultra spf 50 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 Ultra SPF 50 Lotion

☐Active Ingredients

Acobenzone 2.0%, Homosalate 10.0%, Octisalate 5.0%, 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

☐**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 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, silica, aluminum starch octenylsuccinate, behenyl alcohol, butylated PVP, 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, disodium EDTA, butylene glycol

Questions or Comments?

Call toll free 1-800-527-7731

H.E.B Solutions Sunscreen Ultra SPF 50 Lotion

3 FL OZ (89mL)

NDC 37808-956-09

H-E-B Solutions™ sunscreen

ULTRA PROTECTION Sunscreen Lotion

BROAD SPECTRUM SPF 50

SPF 50

- ✓ with **SPECTRA-PLEX®** Photostable UVA / UVB
- ✓ Helps reduce the risk of early skin aging†
- ✓ Fragrance Free
- ✓ Water Resistant (80 minutes)

3 FL OZ (89 mL)

†This non-greasy lotion may help reduce the risk of early skin aging caused by the sun when used as directed with other sun protection measures.

Drug Facts	
Active ingredients	Purpose
Avobenzone 2.0% Homosalate 10.0% Octisalate 5.0% Octocrylene 7.0% Oxybenzone 6.0%	Sunscreen
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MADE WITH PRIDE AND CARE FOR H-E-B®
SAN ANTONIO, TX 78264
MADE IN USA WITH U.S. AND FOREIGN PRINTS

100% GUARANTEE
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.

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0 41220 89895 4

H.E.B Solutions Sunscreen Ultra SPF 50 Lotion

8 FL OZ (237mL)

1/4	NO PRINT	AREA Eye Mark							
All copy must be below the eye-mark									
 <h1 style="font-size: 4em; margin: 0;">ULTRA 50</h1> <p style="font-size: 1.5em; margin: 0;">Ultra Sunscreen</p> <p style="margin: 0;">UVA/UVB Protection Water Resistant (80 minutes) Paraben Free</p> <p style="font-weight: bold; margin: 0;">BROAD SPECTRUM SPF 50</p>   <p style="font-size: 1.5em; margin: 0;">8 FL OZ (237 mL)</p>	<p style="margin: 0;">Dermatologist Tested Oil Free • PABA Free Retinyl Palmitate Free • Fragrance Free Hypoallergenic Contains Aloe, Chamomile Extract, Vitamin E</p> <div style="border: 1px solid black; padding: 5px;"> <p>Drug Facts</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">Active Ingredients</th> <th style="text-align: left; border-bottom: 1px solid black;">Purpose</th> </tr> </thead> <tbody> <tr> <td style="border-right: 1px solid black;">Avobenzone 2%</td> <td rowspan="5" style="vertical-align: middle;">Sunscreen</td> </tr> <tr> <td style="border-right: 1px solid black;">Homosalate 10%</td> </tr> <tr> <td style="border-right: 1px solid black;">Octisalate 5%</td> </tr> <tr> <td style="border-right: 1px solid black;">Octocrylene 7%</td> </tr> <tr> <td style="border-right: 1px solid black;">Oxybenzone 6%</td> </tr> </tbody> </table> <p>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</p> <p>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.</p> <p>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.</p> <p>Other Information • protect this product from excessive heat and direct sun • may stain or damage some fabrics, materials or surfaces</p> <p>Inactive Ingredient(s) water, propylene glycol, silica, aluminum starch octenylsuccinate, behenyl alcohol, butylated PVP, 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, disodium EDTA, butylene glycol</p> <p>Questions or Comments? Call toll free 1-800-527-7731</p> </div> <p style="text-align: center; font-weight: bold; margin: 0;">MADE WITH PRIDE AND CARE FOR H-E-B®, SAN ANTONIO, TEXAS 78204</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  </div> <div style="text-align: center;"> <p style="font-size: 0.8em;">7127-1811</p>  <p style="font-size: 0.8em;">PLEASE RECYCLE</p> </div> </div>	Active Ingredients	Purpose	Avobenzone 2%	Sunscreen	Homosalate 10%	Octisalate 5%	Octocrylene 7%	Oxybenzone 6%
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H.E.B SOLUTIONS SUNSCREEN

ultra spf 50 lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-956
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	70 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-956-09	89 mL in 1 TUBE; Type 0: Not a Combination Product	02/20/2012	
2	NDC:37808-956-12	237 mL in 1 TUBE; Type 0: Not a Combination Product	02/20/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/20/2012	

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(37808-956)

Revised: 3/2020

H.E.B