

## **HILL COUNTRY ESSENTIALS- spf 15 moisturizing 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.*

### **Hill Country Essentials Radiant Skin SPF 15 Moisturizing Lotion**

#### **☐Active ingredients**

Avobenzone 3.0%, Octisalate 2.0%, Octinoxate 7.5%

#### **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 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
- use a water resistant sunscreen if swimming or sweating
- reapply 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 of age: ask a doctor

#### **Other information**

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

#### **Inactive ingredients**

water, C12-C15 alkyl benzoate, glycerin, cetearyl alcohol, dimethicone, glycine soja (soybean) seed extract, bis-phenylpropyl dimethicone, arachidyl alcohol, phenoxyethanol, cetearyl glucoside, panthenol, benzyl alcohol, ethylene/acrylic acid copolymer, behenyl alcohol, steareth-2, fragrance, steareth-21, polyacrylamide, polymethyl methacrylate, arachidyl glucoside, disodium EDTA, methylparaben, C13-14 isoparaffin, ethylparaben, butylparaben, laureth-7, benzalkonium chloride, propylparaben, isobutylparaben, iodopropynyl butylcarbamate, BHT, PEG-4 dilaurate, PEG-4 laurate, PEG-4, mica, silica, titanium dioxide

**Questions or comments?**

Call toll free 1-800-527-7731

Hill Country Essentials Radiant Skin SPF 15 Moisturizing Lotion

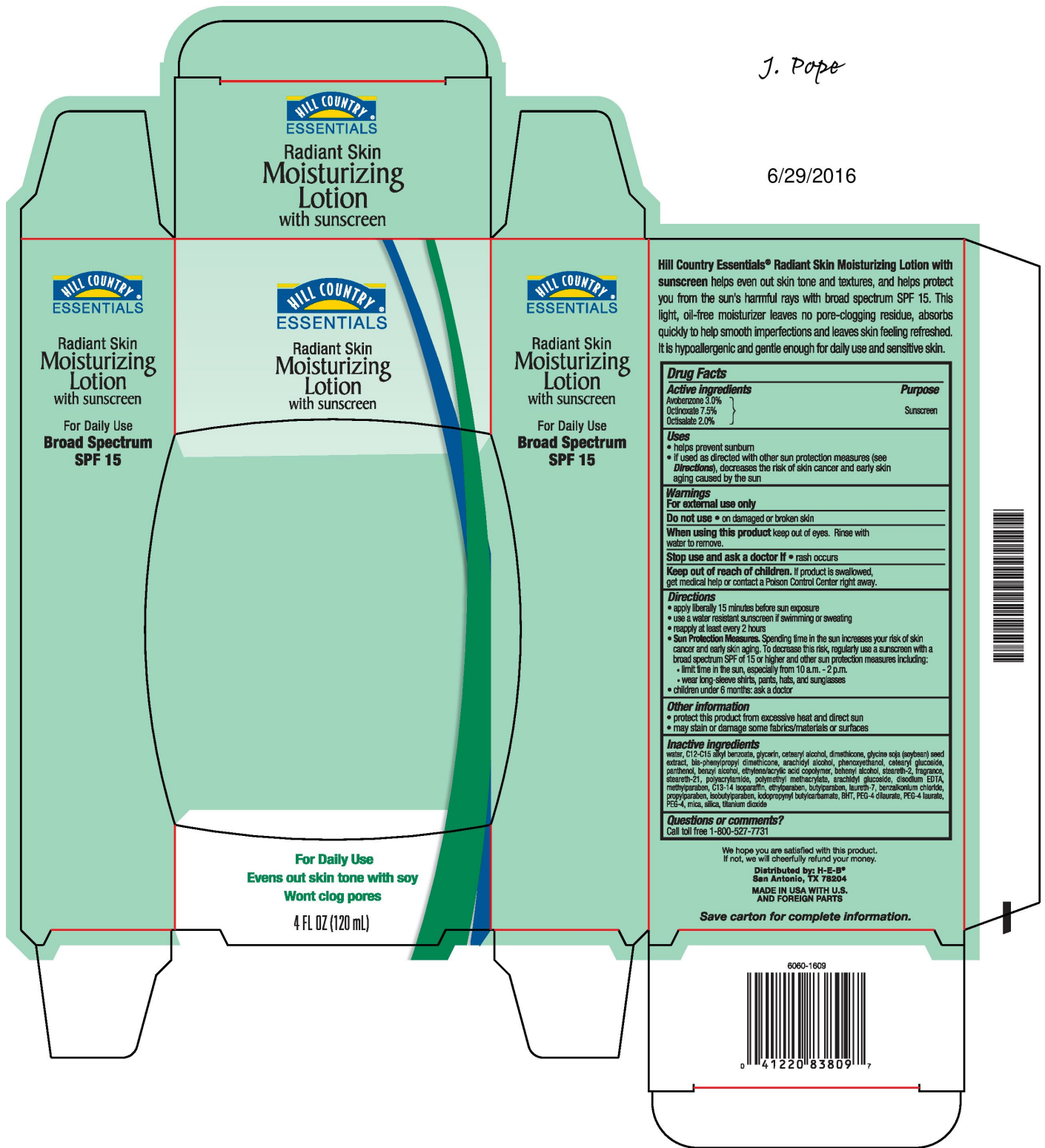
4 FL OZ (120mL)

NDC 37808-985-04



J. Pope

6/29/2016



Hill Country Essentials® Radiant Skin Moisturizing Lotion with sunscreen helps even out skin tone and textures, and helps protect you from the sun's harmful rays with broad spectrum SPF 15. This light, oil-free moisturizer leaves no pore-clogging residue, absorbs quickly to help smooth imperfections and leaves skin feeling refreshed. It is hypoallergenic and gentle enough for daily use and sensitive skin.

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Ambazone 3.0%	Sunscreen
Ocinoxate 7.5%	
Octisalate 2.0%	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>if used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and early skin aging caused by the sun</li> </ul>	
<b>Warnings</b>	
<b>For external use only</b>	
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 product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>use a water resistant sunscreen if swimming or sweating</li> <li>reapply at least every 2 hours</li> <li>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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. - 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses</li> <li>children under 6 months: ask a doctor</li> </ul> </li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>protect this product from excessive heat and direct sun</li> <li>may stain or damage some fabrics/materials or surfaces</li> </ul>	
<b>Inactive Ingredients</b>	
water, C12-15 alkyl benzoate, glycerin, octylalcohol, dimethicone, glycine soja (soybean) seed extract, bis-phenylpropyl dimethicone, arachidyl alcohol, phenoxyethanol, cetearyl glucoside, panthenol, benzyl alcohol, ethyleneacrylic acid copolymer, behenyl alcohol, steareth-2, fragrance, steareth-21, polysilylenes, polybutyl methacrylate, arachidyl glucoside, disodium EDTA, methylparaben, C13-14 isoparaffin, ethylparaben, butylparaben, laureth-7, benzalkonium chloride, propylparaben, isobutylparaben, potassium butylcarbamate, BHT, PEG-4 stearate, PEG-4 laurate, PEG-4, mica, silica, titanium dioxide	
<b>Questions or comments?</b>	
Call toll free 1-800-527-7731	

We hope you are satisfied with this product. If not, we will cheerfully refund your money.

Distributed by: H-E-B®  
San Antonio, TX 78204  
MADE IN USA WITH U.S.  
AND FOREIGN PARTS

Save carton for complete information.

## HILL COUNTRY ESSENTIALS

spf 15 moisturizing lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-985
Route of Administration	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>PANTHENOL</b> (UNII: WV9CM0067Z)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ETHYL PARABEN</b> (UNII: 14255EXE39)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>STEARETH-2</b> (UNII: V56DFE46J5)	
<b>STEARETH-21</b> (UNII: 53J3F32P58)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETEARYL GLUCOSIDE</b> (UNII: 09FUA47KNA)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVV35J00J)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>TRISILOXANE</b> (UNII: 9G1ZW13R0G)	
<b>BIS-PHENYLPROPYL DIMETHICONE (15 CST)</b> (UNII: 4836494CFT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ACRYLIC ACID/ETHYLENE COPOLYMER (600 MPa.S)</b> (UNII: 1PEZ3NLY6I)	
<b>LAURETH-7</b> (UNII: Z95S6G8201)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	
<b>POLYACRYLAMIDE (1500 MW)</b> (UNII: 5D6TC4BRWV)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>IODOPROPYNYL BUTYLCARBAMATE</b> (UNII: 603P14DHEB)	
<b>PEG-4 DILAURATE</b> (UNII: KCR71CW036)	
<b>PEG-4 LAURATE</b> (UNII: AYF4VM3N1Z)	
<b>POLYETHYLENE GLYCOL 200</b> (UNII: R95B8J264J)	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>C13-14 ISOPARAFFIN</b> (UNII: E4F12ROE70)	
<b>BUTYL PARABEN</b> (UNII: 3QPIIU3FV8)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>ISOBUTYL PARABEN</b> (UNII: 0QQJ25X58G)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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1	NDC:37808-985-05	1 in 1 CARTON	07/09/2011	
1	NDC:37808-985-04	120 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part352		07/09/2011	

**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(37808-985)

Revised: 3/2020

H.E.B