

HILL COUNTRY ESSENTIALS- spf 15 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 OIL FREE FACIAL MOISTURIZER SPF 15

Active Ingredients

Octinoxate 7.5%, Octisalate 5.0%, Oxybenzone 3.0%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

☐**Skin Cancer/Skin Aging Alert**☐: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.☐

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

- pump onto hands and apply liberally and evenly to face and neck 15 minutes before sun exposure
- use daily after cleansing
- 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 Ingredient(s)

water, octyldodecyl neopentanoate, glycerin, emulsifying wax NF, glyceryl stearate, PEG-100 stearate, dimethicone, triethanolamine, diazolidinyl urea, methylparaben, ethylparaben, propylparaben, carbomer

Questions or Comments?

Call toll free 1-800-527-7731

HILL COUNTRY ESSENTIALS OIL FREE FACIAL MOISTURIZER SPF 15

4 FL OZ (118mL)

NDC 37808-925-04



Won't clog pores
Hypoallergenic
Fragrance free
Alcohol free

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- **Oil Free** • **Fragrance Free**
- **Alcohol Free** • **Hypoallergenic**
- **Won't Clog Pores**

Drug Facts

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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 US AND FOREIGN PARTS**

HILL COUNTRY ESSENTIALS

spf 15 lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37808-925
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)	
GLYCERIN (UNII: PDC6A3C0OX)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
POLYSORBATE 60 (UNII: CAL22UVI4M)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
PEG-100 STEARATE (UNII: YD01N1999R)
DIMETHICONE (UNII: 92RU3N3Y1O)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
TROLAMINE (UNII: 9O3K93S3TK)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
METHYLPARABEN (UNII: A2I8C7HI9T)
ETHYLPARABEN (UNII: 14255EXE39)
PROPYLPARABEN (UNII: Z8IX2SC1OH)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37808-925-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/04/2018	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/04/2018	

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(37808-925)