

FRUIT OF THE EARTH SPF 4 MOISTURIZING TANNING SUNSCREEN- octinoxate, oxybenzone lotion

Fruit of the Earth, Inc.

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.

Fruit of the Earth, Inc. SPF 4 Moisturizing Tanning Sunscreen Lotion

Active ingredients

Octinoxate 2.0%, Oxybenzone 0.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn • higher SPF gives more sunburn protection

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 product is swallowed, get medical help 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
- children under 6 months: 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 (aqua), C12-15 alkyl benzoate, PEG-8, cetearyl alcohol, acrylates/C12-22 alkyl methacrylate copolymer, aloe barbadensis leaf juice, daucus corota sativa (carrot) root extract, arnica montana flower extract, chamomilla recutita (matricaria) flower extract, germanium maculatum extract, cucumis sativus (cucumber) fruit extract, euphrasia officinalis extract, tilia cordata flower extract, althaea officinalis extract, yucca schidigera extract, dicetyl phosphate, ceteth-10 phosphate, tocopheryl acetate, sodium ascorbyl phosphate, potassium cetyl phosphate, propylene glycol, acrylates/C10-30 alkyl acrylate

crosspolymer, hydrated silica, phenoxyethanol, potassium sorbate, caprylyl glycol, hexylene glycol, triethanolamine, disodium EDTA, fragrance (parfum)

Questions or comment?

Call toll free 1-800-527-7731

Fruit of the Earth, Inc. SPF 4 Moisturizing Tanning Sunscreen Lotion

FRUIT OF THE EARTH®

TAN 4

MOISTURIZING LOTION SUNSCREEN

UVA/UVB PROTECTION SPF 4

WITH ALOE VERA • PARABEN FREE
DERMATOLOGIST TESTED

3 FL OZ (88 ML)

Fruit of the Earth® DARK TANNING SPF 4 Lotion Sunscreen

delivers minimal protection from skin-damaging UVA & UVB rays — UVA/UVB protection teamed up with moisturizing aloe vera and protective antioxidant vitamins C & E. This hypoallergenic sun defense formula dries quickly and easily for even coverage providing SPF 4 protection.

Drug Facts

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Questions or comments?

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Contains Oxybenzone

Fruit of the Earth, Inc.
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Fort Worth, TX 76155
www.fote.com



FRUIT OF THE EARTH SPF 4 MOISTURIZING TANNING SUNSCREEN

octinoxate, oxybenzone lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62217-011 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 20 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|-----------------|
| YUCCA SCHIDIGERA (UNII: 08A0YG3VIC) | |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) | |
| BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P) | |
| CETETH-10 PHOSPHATE (UNII: 4E05O5N49G) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR) | |
| TILIA CORDATA FLOWER (UNII: CFN6G1F6YK) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N) | |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N) | |
| HYDRATED SILICA (UNII: Y6O7T4G8P9) | |
| CARROT (UNII: L56Z1JK48B) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| CHAMOMILE (UNII: FGL3685T2X) | |
| CUCUMBER (UNII: YY7C30VXJT) | |
| EUPHRASIA STRICTA (UNII: C9642I91WL) | |
| ALTHAEA OFFICINALIS ROOT (UNII: TRW2FUF47H) | |
| GERANIUM MACULATUM ROOT (UNII: 93IXI5B6OJ) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62217-011-03 | 88 mL in 1 TUBE; Type 0: Not a Combination Product | 05/16/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 05/16/2017 | |

Labeler - Fruit of the Earth, Inc. (079559467)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| Fruit Of The Earth Research Laboratories, Inc. | | 008193513 | manufacture(62217-011) |

Revised: 8/2017

Fruit of the Earth, Inc.