SHEA MOISTURE SPF 35 MINERAL SUNSCREEN- zinc oxide, titanium dioxide cream CONOPCO INC. D/B/A/ UNILEVER

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.

SHEA MOISTURE SPF 35 VITAMIN E & JOJOBA SEED OIL MINERAL BODY CREAM

Active Ingredients

Zinc Oxide 10%, Titanium Dioxide 3%

Purpose

Sunscreen, Sunscreen

Uses:

- Helps prevent against 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 using and ask a doctor** if rash occur.
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

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 Broad Spectrum SPF value 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**: Ask a doctor

Directions:

- Apply generously and evenly 15 minutes before sun exposure.
- Apply to all skin exposued to the sun.

Reapply:

- After swimming or sweating.
- Immediately after towel drying.
- At least every 2 hours

Other Information:

• Protect this product from excessive heat and direct sun.

Inactive Ingredients:

water, neopentyl glycol diheptanoate, caprylic/capric triglyceride, butyloctyl salicylate, cetyl PEG/PPG-10/1 dimethicone, C30-38 olefin/isopropyl maleate/MA copolymer, sorbitan tristearate, silica, stearyl/octyldodecyl citrate crosspolymer, VP/hexadecen copolymer, phenoxyethanol, magnesium sulfate, aloe barbadensis leaf juice, glycine soja (soybean) seed extract, glycerin, arachidyl alcohol, behenyl alcohol, arachidyl glucoside, stearyl alcohol, tocopherol, avena sativa (oat) kernel extract, glyceryl stearate, simmondsia chinensis (jojoba) seed oil, polysorbate 60, ethylhexylglycerin, citric acid.

Questions?

631-842-8800 or visit www.SheaMoisture.com

SHEA MOISTURE SPF 35 VITAMIN E & JOJOBA OIL MINERAL BODY CREAM 6 FL OZ (177mL)

NDC 64942-1741-1



SHEA MOISTURE SPF 35 MINERAL SUNSCREEN

zinc oxide, titanium dioxide cream

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:64942-1741 Route of Administration TOPICAL

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|----------------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP) | TITANIUM DIO XIDE | 30 mg in 1 mL | | |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 100 mg in 1 mL | | |
| | | | | |

| Inactive Ingredients | |
|---|----------|
| Ingredient Name | Strength |
| CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 5) (UNII: 035JKJ76MT) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3) | |
| ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU) | |
| DOCOSANOL (UNII: 9G10E216XY) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| ANHYDRO US CITRIC ACID (UNII: XF417D3PSL) | |
| OAT (UNII: Z6J799EAJK) | |
| SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| STEARYL/O CTYLDO DECYL CITRATE CROSSPOLYMER (UNII: PN88NW0 KPK) | |
| HEXADECYL POVIDONE (UNII: AG75W62QYU) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| MAGNESIUM SULFATE, UNSPECIFIED FORM (UNII: DE08037SAB) | |
| SO YBEAN (UNII: L7HT8F1ZOD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| WATER (UNII: 059QF0KO0R) | |
| NEOPENTYL GLYCOL DIHEPTANO ATE (UNII: 5LKW3C543X) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4) | |
| JOJOBA OIL (UNII: 724GKU717M) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |

| Packaging | | | |
|--------------------|---|-----------------------------|---------------------------|
| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 NDC:64942-1741-1 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 04/18/2019 | |

| Marketing Information | | | | |
|-------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 04/18/2019 | | |
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Labeler - CONOPCO INC. D/B/A/UNILEVER (001375088)

Registrant - FRUIT OF THE EARTH, INC. (079559467)

| Establishment | | | | | |
|--------------------------|---------|-----------|-------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| FRUIT OF THE EARTH, INC. | | 080086802 | manufacture(64942-1741) | | |