

**RED GECKO BROAD SPECTRUM SPF 30 SUNSCREEN- zinc oxide lotion
Formula 7venz L.L.C.**

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.

RED GECKO™ BROAD SPECTRUM SPF 30 SUNSCREEN

Drug Facts

Active ingredient

Zinc Oxide 18%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see Directions), decreases the risk of 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 Poison Control Center right away.

Directions

- Apply liberally and evenly 15 minutes prior to sun exposure
- Reapply: After 40 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 skin aging. To decrease this risk, regularly

use a sunscreen with a 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-sleeved shirts, pants, hats, and sunglasses.

Other information

- Protect this product from excessive heat and direct sun.

Inactive ingredients

Aloe barbadensis leaf juice, C12-15 alkyl benzoate, caprylic/capric triglyceride, glyceryl stearate, helianthus annuus (sunflower) seed

oil, ricinus communis (castor) seed oil, beeswax, oryza sativa (rice) bran wax, sorbitan sesquioleate, glycerin, cetyl alcohol, stearyl

alcohol, magnesium aluminum silicate, butyrospermum parkii (shea) butter, camellia sinensis flower extract, ilex paraguariensis

leaf extract, rosa canina fruit oil, tocopheryl acetate, carthamus tinctorius (safflower) seed oil, rubus idaeus (raspberry) fruit

extract, squalane, xanthan gum, propanediol, ethylhexylglycerin, potassium sorbate.

Questions?

Call us! (702) 275-6167

REEF SAFE

NON-NANO

BORN ON MAUI

MADE IN USA

Save your skin

Save our reefs

TSA Friendly

Fragrance Free

Distributed by: **Formula 7venz, LLC.**

118 Kupuohi Street Suite C-4

Lahaina, HI 96761

redgeckosunscreen.com

Packaging

Drug Facts

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|-------------------|-----------|
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**BROAD SPECTRUM SPF 30
SUNSCREEN**



NON-NANO
ZINC OXIDE

REEF SAFE


SPF 30




BORN ON MAUI
MADE IN USA

3.4 FL. OZ. (100 ML.)


Save your skin
Save our reefs



Reef
Safe



TSA
Friendly



Fragrance
Free

RED GECKO BROAD SPECTRUM SPF 30 SUNSCREEN

zinc oxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:82086-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 18 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |

| |
|---|
| CASTOR OIL (UNII: D5340Y2I9G) |
| YELLOW WAX (UNII: 2ZA36H0S2V) |
| RICE BRAN (UNII: R60QEP13IC) |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| CETYL ALCOHOL (UNII: 936JST6JCN) |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) |
| MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC) |
| SHEA BUTTER (UNII: K49155WL9Y) |
| CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17) |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) |
| ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ) |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| SAFFLOWER OIL (UNII: 65UEH262IS) |
| RASPBERRY (UNII: 4N14V5R27W) |
| SQUALANE (UNII: GW89575KF9) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| PROPANEDIOL (UNII: 5965N8W85T) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:82086-002-34 | 100 mL in 1 TUBE; Type 0: Not a Combination Product | 07/02/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 07/02/2020 | |

Labeler - Formula 7venz L.L.C. (118069729)

Revised: 7/2021

Formula 7venz L.L.C.