

NATURAL MINERAL FORMULA- zinc oxide lotion
Raining Rose, 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.

Broad Spectrum SPF 30 NATURAL MINERAL FORMULA

DRUG FACTS

Active Ingredients :

Zinc Oxide (18.75%) Non-nanoparticle

Purpose

Sunscreen

Uses

- Helps prevent sunburn

Warnings

- **For External Use Only**
- **Do not use** on damaged or broken skin

Stop use and as a doctor if • rash occurs

When using this product • Keep out of eyes. Rinse well with water to remove.

Keep out of reach of children.

If swallowed, get medical help or call a Poison Control Center right away.

Directions •Apply liberally 15 minutes before sun exposure

- Reapply after 80 minutes of swimming or sweating, •Reapply
- immediately after towel drying. •Reapply 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 protection measures including:

- limit time in the sun, especially from 10a.m. - 2p.m.
- wear long sleeved shirts, pants, hat, and sunglasses.

Inactive Ingredients: Helianthus Annus (Sunflower) Seed Oil*, Cera Alba (Beeswax)*, Simmondsia Chinensis (Jojoba) Seed Oil*, Cocos Nucifera (Coconut) Oil*, non-GMO Tocopherol (Vitamin E).

*Organic Ingredients

Other Information: Protect this product from excessive heat and direct sun.

Product Package Labeling

Dist. by: Raining Rose, Inc., Cedar Rapids, IA 52403

Broad Spectrum SPF 30 Sunscreen

NATURAL MINERAL FORMULA

WATER RESISTANT

(80 MINUTES)

1.5 fl. oz. / 44 ml

L000000

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Made in the USA

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zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0738
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	8.25 g in 44 mL

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
JOJOBA OIL (UNII: 724GKU717M)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0738-1	44 mL in 1 TUBE; Type 0: Not a Combination Product	08/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/16/2019	

Labeler - Raining Rose, Inc. (083819404)

Registrant - Raining Rose, Inc. (083819404)