

**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.*

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**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 Chinensia (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 fl. oz. / 30 ml**

Made in the USA

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

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<p><b>Drug Facts</b></p> <table border="1"><tr><td><b>Active Ingredients:</b></td><td><b>Purpose</b></td></tr><tr><td>Zinc Oxide (18.75%) Non-nanoparticle.....</td><td>Sunscreen</td></tr></table> <p><b>Uses</b> • Helps prevent Sunburn</p> <p><b>Warnings:</b></p> <ul style="list-style-type: none"><li>• For external use only</li><li>• Do not use on damaged or broken skin</li><li>• Stop use and ask a doctor if • rash occurs</li><li>• When using this product • keep out of eyes. Rinse with water to remove. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li></ul> <p><b>Directions</b> • 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. <b>Ask a doctor</b></p>	<b>Active Ingredients:</b>	<b>Purpose</b>	Zinc Oxide (18.75%) Non-nanoparticle.....	Sunscreen	<p><b>Broad Spectrum SPF 30 Sunscreen</b> NATURAL MINERAL FORMULA</p> <p><b>WATER RESISTANT (80 MINUTES)</b></p> <p><b>1 fl. oz. / 30 ml</b> Made in the USA</p>	<p><b>Drug Facts (Continued)</b></p> <p><b>Sun Protection Measures</b> 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 10a.m. - 2p.m. • wear long sleeved shirts, pants, hats and sunglasses.</p> <p><b>Inactive Ingredients:</b> Helianthus Annuus (Sunflower) Seed Oil*, Cera Alba (Beeswax)*, Simmondsia Chinensis (Jojoba) Seed Oil*, Cocos Nucifera (Coconut) Oil*, non-GMO Tocopherol (Vitamin E), *Organic Ingredients</p> <p><b>Other Information</b> Protect this product from excessive heat and direct sun. <i>Protect your skin from the sun, while nourishing it with natural vegetable glycerin and the soothing effects of aloe vera.</i></p> <p>Dist. by: Raining Rose, Inc. Cedar Rapids, IA 52403</p> <p>L000000</p>
<b>Active Ingredients:</b>	<b>Purpose</b>					
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<b>NATURAL MINERAL FORMULA</b>			
zinc oxide lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65692-0747
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	5.625 g in 30 mL
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	SUNFLOWER OIL (UNII: 3W1JG795Y)		
	YELLOW WAX (UNII: 2ZA36H0S2V)		

<b>JOJOBA OIL</b> (UNII: 724GKU717M)				
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)				
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)				
<b>Product Characteristics</b>				
<b>Color</b>	white	<b>Score</b>		
<b>Shape</b>		<b>Size</b>		
<b>Flavor</b>		<b>Imprint Code</b>		
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0747-1	30 mL in 1 TUBE; Type 0: Not a Combination Product	08/19/2019	
<b>Marketing Information</b>				
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)