

SPF 30 MINERAL SUN STICK- zinc oxide stick
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.

SPF 30 Mineral Sun Stick

DRUG FACTS

Active Ingredients:

Zinc Oxide 18.0%

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

- Use a water resistant sunscreen if swimming or sweating
- 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: Sunflower Seed Oil*, Beeswax*, Olive Oil*, Tocopherol, aloe vera leaf extract, canola oil. *Organic Ingredient

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

Product Package Labeling

☐ **PEEL HERE FOR DRUG FACTS**

Broad Spectrum

SPF 30 Mineral Sun Stick

Made in the USA

Net Wt. 0.6.oz.

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

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SAFETY SEAL

▼ PEEL HERE FOR DRUG FACTS

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SPF 30 Mineral Sun Stick**

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Drug Facts (continued)

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Other Information

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SAFETY SEAL

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

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SPF 30 MINERAL SUN STICK

zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-0848
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	3.06 g in 17 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CANOLA OIL (UNII: 331KBJ17RK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-0848-1	17 g in 1 TUBE; Type 0: Not a Combination Product	08/21/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/21/2019	

Labeler - Raining Rose, Inc. (083819404)

Registrant - Raining Rose, Inc. (083819404)

Revised: 8/2019

Raining Rose, Inc.