

**SPF 50 MINERAL POWDER SUNSCREEN- titanium dioxide, zinc oxide powder  
Smalls Brand LLC DBA Roe Wellness**

*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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**Roe Wellness Powder sunscreen**

**Active Ingredients:**

Titanium Dioxide 23.9%

Zinc Oxide 24.1 %

**Purpose:** Sunscreen

Uses:

- Helps prevent sunburn

**Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if rash occurs

**Warning:**

- **For external use only.** Do not use on broken or damaged skin
- When using this product keep out of eyes. Rinse with water to remove.

**Directions:**

- Apply liberally 15 minutes before sun or water exposure. Works best on moisturized skin. Reapply:
- After 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- Children under 6 months: Ask a doctor

**Inactive ingredients:** Silica, Mica, Polymethyl Methacrylate, Ascorbic Acid (Vitamin C), Ceramide EOP, Sodium Hyaluronate (Hyaluronic Acid), Tocopherol (Vitamin E), Camellia Sinensis Leaf Extract, CI 77492, CI 77491

roe wellness

spf 50 mineral powder

broad spectrum

0.21 oz 6g

30mm

**committed to clean.**  
gentle • fragrance-free • vegan

**Drug Facts**

**Active Ingredients:**

Titanium Dioxide 23.9%  
Zinc Oxide 24.1%

**Purpose:** Sunscreen

**Uses:** ■ Helps prevent sunburn.

**Other Information:** ■ Sun alert: Limiting sun exposure, wearing protective clothing, using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.

**Warning:** ■ For external use only. Do not use on broken or damaged skin. Stop use and ask a doctor if rash occurs. When using this product keep out of eyes. Rinse with water to remove. ■ Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

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**VEGAN**



**SUSTAINABLE  
PACKAGING**



**COMPLETELY  
CLEAN**



**CRUELTY  
FREE**

**roe**  
wellness

**our mission**

To provide high quality, clean, and luxurious products that parents can trust.

**spf 50  
mineral  
powder**

**broad spectrum**

0.21oz • 6g

**DISTRIBUTED BY**  
roe Wellness  
Draper, UT 84020  
roewellness.com

117mm

30mm

# SPF 50 MINERAL POWDER SUNSCREEN

titanium dioxide, zinc oxide powder

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83369-001
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	23.9 g in 100 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MICA</b> (UNII: V8A1AW0880)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>CERAMIDE 1</b> (UNII: 5THT33P7X7)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>POLY(METHYL METHACRYLATE; 450000 MW)</b> (UNII: Z47NNT4J11)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83369-001-01	6 g in 1 CARTON; Type 0: Not a Combination Product	04/13/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	04/13/2023	

**Labeler** - Smalls Brand LLC DBA Roe Wellness (058449263)