(RE) SETTING 100% MINERAL POWDER DEEP BROAD SPECTRUM SPF 35- zinc oxide powder
Supergoop, LLC

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.

(Re) Setting 100% mineral Powder Deep Broad Spectrum SPF 35

Active Ingredients Purpose

Zinc Oxide 24.7% Sunscreen

Uses

- Helps prevent sunburn
- If used as directed with oher sun protection measures(see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

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

Stop use and ask a doctor if rash occurs.

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.

Directions

- Apply generously and evenly 15 minutes before sun exposure
- Use a water-resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours

- **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 your time in the sun, especially from 10 a.m. – 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses •

- Children under 6 months of age: ask a doctor.

Inactive Ingredients

Calcium Aluminum Borosilicate, Silica, Trimethylsiloxysilicate, Calcium Sodium Borosilicate, Polymethyl Methacrylate, Lauroyl Lysine, Polyglyceryl-10 Pentaisostearate, Boron Nitride, Triethoxycaprylylsilane, Ethylhexylglycerin, Nylon-6/12, Sodium Dehydroacetate, Olive Glycerides, Ascorbyl Palmitate, Ceramide 3, Iron Oxides (CI 77492, CI 77491, CI 77499)

(RE) Setting 100% Mineral Powder SPF 35 PA +++

0.12 oz/ 4.25 g

(RE) SETTING 100% MINERAL POWDER DEEP BROAD SPECTRUM SPF 35

zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75936-168
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.7 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
LAUROYL LYSINE (UNII: 113171Q70B)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CERAMIDE 3 (UNII: 4370DF050B)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-168-01	4.25 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	09/14/2020	
2	NDC:75936-168-02	4.25 g in 1 JAR; Type 0: Not a Combination Product	09/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/14/2020	

Labeler - Supergoop, LLC (117061743)

Revised: 10/2022 Supergoop, LLC