(RE) SETTING 100% MINERAL POWDER TRANSLUCENT BROAD SPECTRUM SUNSCREEN 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 Translucent Broad Spectrum Suncreen SPF 35

Zinc Oxide 24.7% Purpose Sunscreen

- Sunscreen
- Helps prevent sunburn
- If used as directed with other 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.

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

- apply generously and evenly 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- **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 time in the sun, especially from 10 a.m. - 2 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglassess
- Children under 6 months: Ask a doctor

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

Supergoop!

(RE) SETTING

100% Mineral Powder

SPF 35

Translucent

Broad Spectrum Sunscreen SPF 35 PA+++

0.15 oz./4.25 g

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

zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75936-169
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
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
LAUROYL LYSINE (UNII: 113171Q70B)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
CERAMIDE 3 (UNII: 4370DF050B)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-169-01	4.25 g in 1 BOTTLE; Type 0: Not a Combination Product	09/08/2020	
2	NDC:75936-169-02	4.25 g in 1 JAR; Type 0: Not a Combination Product	09/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	09/08/2020	

Labeler - Supergoop, LLC (117061743)

Establishment

Name	Address	ID/FEI	Business Operations

Port Jervis Laboratories, Inc		001535103	manufacture(75936-169)