(GLOW)SETTING 100% MINERAL POWDER 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.

(Glow)Setting 100% Mineral Powder SPF 35

(Glow)setting 100% Mineral Powder

Zinc Oxide 2.4% Sunscreen

Uses

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

- **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

Directions

• 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 sunglasses

• Children under 6 months: Ask a doctor

Warnings

- **For external use only**
- **Do not use** on damaged or broken skin
- **Stop use and ask a doctor** if rash occurs
- **When using this product** keep out of eyes
- Rinse with water to remove

Inactive Ingredients

Synthetic Fluorphlogopite, Silica, Trimethylsiloxysilicate, Calcium Aluminum Borosilicate, Polymethyl Methacrylate, Calcium Sodium Borosilicate, Boron Nitride, Polyglyceryl-10 Pentaisostearate, Lauroyl Lysine, Triethoxycaprylylsilane, Ethylhexylglycerin, Water

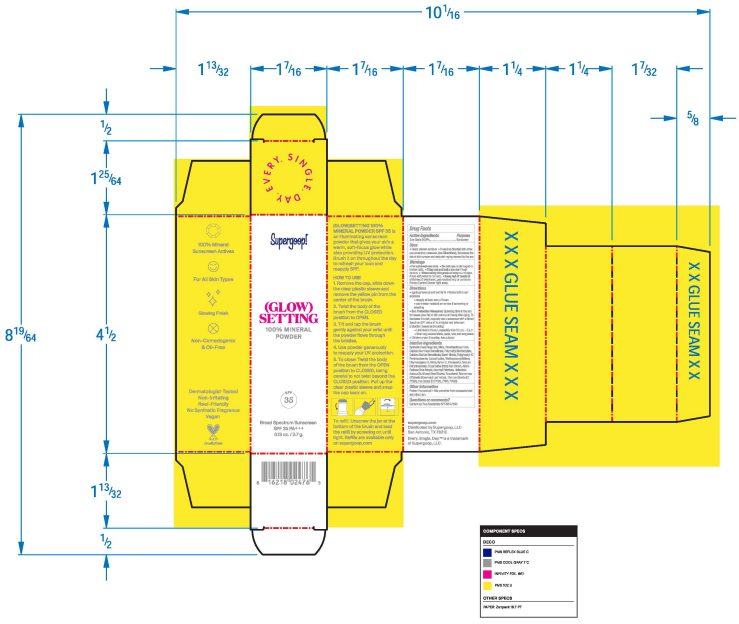
(Aqua), Nylon-12, Propanediol, Sodium Dehydroacetate, Oryza Sativa (Rice) Bran Extract, Aletris Farinosa Root Extract, Ascorbyl Palmitate, Helianthus Annuus (Sunflower) Seed Extract, Tocopherol, Rosmarinus Officinalis (Rosemary) Leaf Extract, Titanium Dioxide (Cl 77891), Iron Oxides (Cl 77492, 77491, 77499)

(Glow)Setting 100% Mineral Powder

SPF 35

Broad Spectrum Sunscreen

0.13 oz. / 3.7 g.



(GLOW)SETTING 100% MINERAL POWDER SPF 35

zinc oxide powder

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75936-603
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	24.9 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	

HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
MAGNESIUM POTASSIUM ALUMINOSILICATE FLUORIDE (UNII: YK3DC63Y5M)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
NYLON-12 (UNII: 446U8J075B)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLY(METHYL METHACRYLATE; 450000 MW) (UNII: Z47NNT4J11)	
BORON NITRIDE (UNII: 2U4T60A6YD)	
LAUROYL LYSINE (UNII: 113171Q70B)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALETRIS FARINOSA ROOT (UNII: O021JGR97X)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
CALCIUM ALUMINUM BOROSILICATE (UNII: 3JRB8A35M0)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRICLATE CALCIUM SODIUM (UNII: U7G9U9300W)	
POLYGLYCERYL-10 PENTASTEARATE (UNII: PMX5872701)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ROSMARINUS OFFICINALIS FLOWER (UNII: NR1A27F29O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-603-02	1 in 1 BOX	10/18/2022	
1	NDC:75936-603-01	3.7 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/18/2022	

Labeler - Supergoop, LLC (117061743)

Revised: 10/2022 Supergoop, LLC