

SUNNYSCREEN SPF 50- titanium dioxide, zinc oxide spray
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.

Sunnyscreen SPF 50 Spray for babies + Kiddos

Active Ingredient Purpose

Titanium Dioxide 10% Sunscreen

Zinc Oxide 12% Sunscreen

Uses

- 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 product is 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
- Reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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

Aqua (Deionized water), Ascorbyl Palmitate, Butyloctyl Salicylate, Calendula Officinalis Extract, Camellia Sinensis (Green Tea) Extract, Caprylic/Capric Triglyceride, Capryl/Caprylyl Glucoside, Chamomilla Recutita (Chamomile) Extract, Cocos Nucifera (Coconut) Oil, Daucus Carota Sativa (Carrot) Extract, Glycerin, Glyceryl Caprylate, Glyceryl Stearate Citrate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Oil, Mangifera Indica (Mango) Butter, Polyhydroxystearic Acid, Punica Granatum

(Pomegranate) Extract, Stearic Acid, Tocopherol (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

Supergoop

Sunnyscreen SPF 50 spray for babies + kiddos

Broad Spectrum Sunscreen SPF 50

Water Resistant (80 minutes)

3.4 fl oz./100 ml



SUNNYSCREEN SPF 50

titanium dioxide, zinc oxide spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75936-252
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	10 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	12 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength

MATRICARIA CHAMOMILLA (UNII: G0R4UBI2ZZ)
COCONUT OIL (UNII: Q9L0O73W7L)
WATER (UNII: 059QF0KO0R)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)
TOCOPHEROL (UNII: R0ZB2556P8)
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
STEARIC ACID (UNII: 4ELV7Z65AP)
XANTHAN GUM (UNII: TTV12P4NEE)
PROPANEDIOL (UNII: 5965N8W85T)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)
GLYCERIN (UNII: PDC6A3C0OX)
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75936-252-01	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/02/2019	

Labeler - Supergoop, LLC (117061743)