

**SPF 30 MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream  
Malin and Goetz Inc**

*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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**(Malin+Goetz) SPF 30 mineral Sunscreen**

Active Ingredient Purpose

Titanium Dioxide 3.71% Sunscreen

Zinc Oxide 2.71% 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

**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 liberally and evenly 15 minutes before sun exposure
- Children under 6 months of age: ask a doctor

**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 10a.m. - 2 p.m.

- wear long-sleeved shirts, pants, hats, and sunglasses
- reapply after 40 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours

*Inactive ingredients*

Water/Aqua/Eau, Glycerin, Caprylic/Capric Triglyceride, Butyrospermum Parkii (Shea) Butter, Niacinamide, Coconut Alkanes, Alumina, Glycogen, Isohexadecane, Polysorbate 60, Sorbitan Isostearate, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate

Copolymer, Sodium Hyaluronate, Diethylhexyl Syringlidene malonate, Triethoxycaprylylsilane, Ursolic Acid, Stearic Acid, Polyhydroxystearic Acid, hydrogenated Lecithin, Benzyl Alcohol, Phenoxyethanol, Tocopheryl Acetate, Coco-Caprylate/Caprate, Aminomethyl Propanol, Xanthan Gum, Citric Acid.

(Malin+Goetz)

spf 30 mineral sunscreen

Broad Spectrum

Water-Resistant 40 minutes

1.7 fl.oz./50 ml

**Drug Facts**

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**Drug Facts (cont.)**

**Other information**  
 • Protect the product in this container from excessive heat and direct sun.

**Inactive ingredients**  
 Water/Aqua/Eau, Glycerin, Caprylic/Capric Triglyceride, Butyrospermum Parifi (Shea) Butter, Niacinamide, Coconut Alkanes, Alumina, Glycogen, Isohexadecane, Polyisobutylate 60, Sorbitan Isostearate, Hydroxyethyl Acrylate/Sodium Acrylyldimethyl Taurate Copolymer, Sodium Hyaluronate, Diethylhexyl Syninglidene malonate, Triethoxycaprylylsilane, Ursolic Acid, Stearic Acid, Polyhydroxystearic Acid, Hydrogenated Lecithin, Benzyl Alcohol, Phenoxethanol, Tocopheryl Acetate, Coco-Caprylate/Caprate, Aminomethyl Propanol, Xanthan Gum, Citric Acid.

# (MALIN+GOETZ)

## spf 30 mineral sunscreen.

BROAD SPECTRUM.  
 WATER-RESISTANT 40 MINUTES—FM-137-50.

1.7fl.oz./50ml

**A 100% MINERAL ACTIVE SUNSCREEN WITH SPF 30 PROTECTION. OUR LIGHTWEIGHT FORMULA HELPS DEFEND AGAINST HARMFUL UVA+UVB RAYS. ANTIOXIDANT RICH INGREDIENTS HELP TO BALANCE, BRIGHTEN AND HYDRATE SKIN. WHILE PROTECTING AGAINST ENVIRONMENTAL AGGRESSORS. EASILY APPLIES AND ABSORBS INTO SKIN. RESIDUE AND CAST-FREE. FOR ALL SKIN TYPES. REEF-SAFE. DISTRIBUTED BY MALIN+GOETZ INC., 300 SEVENTH AVE., NEW YORK, NY 10001, TEL +1 212 244 7771, WWW.MALIN+GOETZ.COM. MADE IN USA. MALIN+GOETZ®**





## SPF 30 MINERAL SUNSCREEN

titanium dioxide, zinc oxide cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53634-128
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.71 g in 100 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	2.71 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>DIETHYLHEXYL SYRINGYLIDENEMALONATE</b> (UNII: 3V5U97P248)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>SORBITAN ISOSTEARATE</b> (UNII: 01S2G2C1E4)	
<b>URSOLIC ACID</b> (UNII: P3M2575F3F)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>HYDROGENATED SOYBEAN LECITHIN</b> (UNII: H1109Z9J4N)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%)</b> (UNII: 86FQE96TZ4)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)	
<b>AMINOMETHYLPROPANOL</b> (UNII: LU49E6626Q)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)	
<b>GLYCOGEN</b> (UNII: 309GSC92U1)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53634-128-01	50 mL in 1 TUBE; Type 0: Not a Combination Product	12/15/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/15/2022	

**Labeler** - Malin and Goetz Inc (138615930)

