

**ANTIOXIDANT TINTED MINERAL SUNSCREEN BROAD SPECTRUM SPF30-
titanium dioxide and zinc oxide cream
Skinhealth Studios 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.

Antioxidant MineralSunscreen Broad Spectrum SPF30

DRUG FACTS:

ACTIVE INGREDIENTS

Titanium Dioxide 7.75%, Zinc Oxide 10.0%.

Purpose

Sunscreen

USES

Helps prevent sunburn.

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. **Stop use and ask a doctor** if rash occurs.

Keep out of reach of children.

DIRECTIONS

Apply to all skin exposed to the sun. *Apply liberally and evenly 15 minutes before sun exposure. *Reapply at least every 2 hours. *Use a water-resistant sunscreen if swimming or sweating. *For 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 time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses.

INACTIVE INGREDIENTS

Water (Aqua), Caprylic/Capric Triglyceride, Butyloctyl Salicylate, Glycerin, Dimethicone, Styrene/Acrylates Copolymer, Coco-Caprylate/Caprates, Aluminum Stearate, Carthamus

Tinctorius Oleosomes, Polyhydroxystearic Acid, Aloe Barbadensis Leaf Juice, Polygonum Aviculare Extract, Tocopheryl Acetate, Perilla Frutescens Extract, Vitis Vinifera Fruit Cell Extract, Lepidium Sativum Sprout Extract, Squalane, Cetearyl Alcohol, Isononyl Isononanoate, Coco-Glucoside, Pentylene Glycol, Behenyl Alcohol, Xanthan Gum, Triethoxycaprylylsilane, Arachidyl Glucoside, Simmondsia Chinensis (Jojoba) Seed Oil, Stearic Acid, Sucrose Stearate, Phenethyl Alcohol, Tetrahexyldecyl Ascorbate, Glyceryl Caprylate, Ethylene/Propylene/Styrene Copolymer, Sorbitan Oleate, Polyglyceryl-2 Caprate, Propanediol, Alumina, Arachidyl Alcohol, Iron Oxides (CI 77492, CI 77491, CI 77499).

OTHER INFORMATION

Protect the product in this container from excessive heat and direct sun.

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83200-0650
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	7.75 g in 100 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERIN (UNII: PDC6A3C0OX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
COCOYL CAPRYLOCAPRATE (UNII: 8D9H4QU99H)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
CARTHAMUS TINCTORIUS SEED OLEOSOMES (UNII: 9S60Q72309)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGONUM AVICULARE TOP (UNII: ZCD6009IUF)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GARDEN CRESS SPROUT (UNII: PWQ18YNR62)	
SQUALANE (UNII: GW89575KF9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
COCO GLUCOSIDE (UNII: ICS790225B)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
DOCOSANOL (UNII: 9G1OE216XY)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ARACHIDYL GLUCOSIDE (UNII: 6JVV35JOOJ)	
JOJOBA OIL (UNII: 724GKU717M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE STEARATE (UNII: 274KW0050M)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYGLYCERYL-2 CAPRATE (UNII: JX7WXJ41DH)	
PROPANEDIOL (UNII: 5965N8W85T)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83200-0650-2	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2023	

Labeler - Skinhealth Studios LLC (046550958)

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Skinhealth Studios LLC