

NATURAL MINERAL SUNSCREEN- titanium dioxide, zinc oxide lotion
Sarati International, Inc.

Active Ingredients

Active Ingredients:

Titanium Dioxide 4.7%

Zinc Oxide 9.5%

Purpose

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

Warnings:

- **For external use only**

Keep out of reach of children.

If product is swallowed, get medical help or contact a Poison Control Center right away

Directions:

- Apply liberally and evenly 15 minutes before sun exposure. Apply to all skin exposed to the sun.
- Reapply
- after 40 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 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.

Alumina, Behentrimonium Methosulfate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglycerides, Cetearyl Alcohol, Coffea Arabica (Coffee) Fruit Extract, Deionized Water, Diisostearoyl Polyglyceryl-3 Dimer Dilinoleate, Disodium EDTA, Distearidimonium Hectorite, Ethylhexylglycerin, Ferulic Acid, Glycerin, Hydrogenated Ethylhexyl Olivatate, Hydrogenated Olive Oil Unsaponifiables, Isohexdecane, Niacinamide, PEG-30 Dipolyhydroxystearate, Phenoxyethanol, Polyhydroxystearic Acid, Propanediol, Propylene Carbonate, Raspberry Ketone, Sodium Chloride, Stearic Acid, Triethoxycaprylylsilane

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

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.

This mineral sunscreen for face and body with zinc oxide and titanium dioxide leaves skin feeling protected.

Drug Facts	
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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. If product is swallowed, get medical help or contact a Poison Control Center right away.	
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Inactive Ingredients: Alumina, Behentrimonium Methosulfate, C12-15 Alkyl Benzoate, Caprylic/Capric Triglycerides, Cetearyl Alcohol, Coffea Arabica (Coffee) Fruit Extract, Deionized Water, Diisostearyl Polyglyceryl-3 Dimer Dilinoleate, Disodium EDTA, Distearidimonium Hectorite, Ethylhexylglycerin, Ferulic Acid, Glycerin, Hydrogenated Ethylhexyl Olivate, Hydrogenated Olive Oil Unsaponifiables, Isohexadecane, Niacinamide, PEG-30 Dipolyhydroxystearate, Phenoxyethanol, Polyhydroxystearic Acid, Propanediol, Propylene Carbonate, Raspberry Ketone, Sodium Chloride, Stearic Acid, Triethoxycaprylylsilane	

Manufactured by: Sarati International, Inc. Los Fresnos TX 78566
www.saratiprivatelabel.com

STELLAR™



SUNSCREEN
Broad Spectrum SPF 30
Water Resistant
(40 minutes)

30

Net Wt. 3.4 fl. oz.

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(40 minutes)

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NATURAL MINERAL SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:67676-009

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.95 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	9.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM OXIDE (UNII: LMI26O6933)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
WATER (UNII: 059QF0KO0R)	
DIISOSTEAROYL POLYGLYCERYL-3 DIMER DILINOLEATE (UNII: G3232Z5S2O)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FERULIC ACID (UNII: AVM951ZWST)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
4-(P-HYDROXYPHENYL)-2-BUTANONE (UNII: 7QY1MH15BG)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYDROGENATED ETHYLHEXYL OLIVATE (UNII: JBH5K4WD8L)	
HYDROGENATED OLIVE OIL UNSAPONIFIABLES (UNII: B8MIX97W95)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
NIACINAMIDE (UNII: 25X51I8RD4)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67676-009-01	100 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/16/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC Monograph Drug	M020	09/16/2024	
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Labeler - Sarati International, Inc. (160219770)

Registrant - Sarati International, Inc (160219770)

Establishment

Name	Address	ID/FEI	Business Operations
Sarati International, Inc.		160219770	manufacture(67676-009)

Revised: 4/2024

Sarati International, Inc.