

## **MILKY MINERAL SUN SERUM- titanium dioxide and zinc oxide lotion** **Synchronicity Spa, Inc. DBA Suntegrity**

*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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### **MILKY MINERAL SUN SERUM SPRAY**

#### **Drug Facts**

<b>Active Ingredient</b>	<b>Purpose</b>
Titanium Dioxide (Non-Nano) 7.2%	Sunscreen
Zinc Oxide (Non-Nano) 9.5%	Sunscreen

#### **Uses**

- helps prevent sunburn

#### **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.
- **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

- Shake well. Do not spray on face. If using on face, spray onto hands and rub on skin.
- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- Children under 6 months: 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 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 & sunglasses

#### **Inactive Ingredients**

Carthamus Tinctorius (Safflower) Seed Oil, Coconut Alkanes (And) Coco-

Caprylate/Caprates, Caprylic/Capric Triglyceride, Helianthus Annuus (Sunflower) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Pongamia Glabra (Karanja) Seed Oil, Olea Europaea (Olive) Fruit Oil, Argania Spinosa (Argan) Kernel Oil, Stearic Acid, Polyhydroxystearic Acid, Tocopheryl Acetate (Vitamin E), Carica Papaya (Papaya) Fruit Extract, Manifera Indica (Mango) Fruit Extract Alumina, Oryza Sativa (Rice) Bran Extract, Bisabolol, Helianthus Annuus (Sunflower) Extract, <sup>1</sup>Squalane, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol,

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1 From Sugarcane

## **Uses**

- protect this product from excessive heat & direct sun

Distributed By: Suntegrity® Skincare Las Vegas, NV 89128

## **PRINCIPAL DISPLAY PANEL - 100 ML Bottle Label**

sun  
tegrity®

MILKY MINERAL

SUN SERUM SPRAY

FOR FACE & BODY

BROAD SPECTRUM SPF 50

SPF  
50

WITH ARGAN & KARANJA OIL

MANGO PAPAYA SCENT

Light, Non-Sticky Texture

Vegan | Reef Friendly

3.4 FL OZ (100 ML)

Paraben, Phthalates, Propylene Glycol, Mineral Oil, Synthetic Dyes, Sulfates, PABA, Nanoparticles, Silicones, and Chemical UV Absorbers

**Drug Facts**

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**Inactive Ingredients:** Carthamus Tinctorius (Safflower) Seed Oil, Coconut Alkanes (And) Coco-Caprylate/Caprate, Caprylic/Capric Triglyceride, Helianthus Annuus (Sunflower) Seed Oil, Vitis Vinifera (Grape) Seed Oil, Pongamia Glabra (Karanja) Seed Oil, Olea Europaea (Olive) Fruit Oil, Argania Spinosa (Argan) Kernel Oil, Stearic Acid, Polyhydroxystearic Acid, Tocopheryl Acetate, Vitamin E, Carica Papaya (Papaya) Fruit Extract, Manihota Indica (Mango) Fruit Extract, Alumina, Oryza Sativa (Rice) Bran Extract, Bieboldi, Helianthus Annuus (Sunflower) Extract, \*Squalene, Rosmarinus Officinalis (Rosemary) Leaf Extract, Tocopherol, \*From Sugarcane

**Uses**  
 • protect this product from excessive heat & direct sun



**MILKY MINERAL  
SUN SERUM SPRAY**  
FOR FACE & BODY

BROAD SPECTRUM SPF 50

**SPF 50**

WITH ARGAN & KARANJA OIL

SHAKE, SPRAY, RUB! For Face: spray on hands first.

[www.SuntegritySkincare.com](http://www.SuntegritySkincare.com)

Distributed By: Suntegrity® Skincare Las Vegas, NV 89128



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**MANGO PAPAYA SCENT**

Light, Non-Sticky Texture  
Vegan | Reef Friendly

3.4 FL OZ (100 ML)

<b>MILKY MINERAL SUN SERUM</b>			
titanium dioxide and zinc oxide lotion			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69949-400
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
Ingredient Name	Basis of Strength	Strength	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	72 mg in 1 mL	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	95 mg in 1 mL	
<b>Inactive Ingredients</b>			
Ingredient Name	Strength		
<b>SAFFLOWER OIL</b> (UNII: 65UEH262IS)			
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)			
<b>COCOYL CAPRYLOCAPRATE</b> (UNII: 8D9H4QU99H)			
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)			
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)			
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)			
<b>KARUM SEED OIL</b> (UNII: 62160PU6FJ)			
<b>OLIVE OIL</b> (UNII: 6UYK2WLWLE)			

<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PAPAYA</b> (UNII: KU94FIY6JB)
<b>MANGO</b> (UNII: I629I3NR86)
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)
<b>RICE BRAN</b> (UNII: R60QEP13IC)
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)
<b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>ROSEMARY</b> (UNII: IJ67X351P9)
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69949-400-01	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/01/2022	

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2022	

**Labeler** - Synchronicity Spa, Inc. DBA Suntegrity (079164130)

Revised: 6/2022

Synchronicity Spa, Inc. DBA Suntegrity