

## **SQUALANE PLUS MINERAL SPF 45- titanium dioxide and zinc oxide cream**

**Amyris, 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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### **Squalane plus Mineral SPF 45**

#### ***Drug Facts***

#### **Active Ingredients**

Titanium Dioxide 4.069%

Zinc Oxide 7%

#### **Purpose**

Sunscreen

#### **Uses**

- Helps prevent sunburn
- If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer & early signs of aging caused by the sun.

#### **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 swallowed, get medical help or contact a poison control center right away.

#### **Directions**

- Apply liberally and evenly to face and neck 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 value of SPF 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.

#### **Inactive ingredients**

Water, Caprylic/Capric Triglyceride, Squalane, Polyglyceryl-3 Sorbityl Linseedate, Cetyl Dimethicone, Dimethicone, Polymethylsilsesquioxane, Glycerin, Styrene/Acrylates Copolymer,

Thermus Thermophilus Ferment, Polyhydroxystearic Acid, Synthetic Fluorophlogopite, Sodium Chloride, Hydroxyacetophenone, Tocopheryl Acetate, Saccharide Isomerate, Caramel, Pentylene Glycol, 1,2-Hexanediol, Caprylyl Glycol, Distearidimonium Hectorite, Triethoxycaprylylsilane, Bisabolol, Benzylidene Dimethoxydimethylindanone, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Zingiber Officinale (Ginger) Root Extract

**Other Information**

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

**Questions or Comments?**

Call toll free 1-844-688-5885

**PRINCIPAL DISPLAY PANEL - 50 ML Tube Carton**

BIOSSANCE

SQUALANE +  
MINERAL SPF 45

BROAD SPECTRUM  
UVA/UVB FACIAL  
SUNSCREEN LOTION

45

Protects, Primes  
& Hydrates Face

50ML/1.6907 FL. OZ.



BIOSSANCE.:

### SQUALANE + MINERAL SPF 45

A LIGHTWEIGHT, FAST-ABSORBING FACE LOTION THAT DEFENDS AGAINST UVA/UVB RAYS, ENVIRONMENTAL STRESSORS AND POLLUTION—LEAVING SKIN MOISTURIZED AND PERFECTLY PREPPED FOR MAKEUP.

#### DIRECTIONS:

Add one pump to fingertips and spread evenly across face and neck. Can be used under makeup.

#### Drug Facts

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Titanium Dioxide 4.065%	Sunscreen
Zinc Oxide 7%	

**Uses** • Helps prevent sunburn • If used as directed with other sun protection measures (see **Directions**), decreases the risk of skin cancer & early signs of aging caused by the sun.

**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 swallowed, get medical help or contact a poison control center right away.

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**Inactive ingredients** Water, Caprylic/Capric Triglyceride, Squalane, Polyglyceryl-3 Sorbitol Linseedate, Cetyl Dimethicone, Dimethicone, Polymethylsilsesquioxane, Glycerin, Styrene/Acrylates Copolymer, Thermus Thermophilus Ferment, Polyhydroxystearic Acid, Synthetic Fluorphlogopite, Sodium Chloride, Hydroxyacetophenone, Tocopheryl Acetate, Saccharide Isomerate, Caramel, Pentylene Glycol, 1,2-Hexanediol, Caprylyl Glycol, Distearidimonium Hectorite, Triethoxycaprylylsilane, Bisabolol, Benzylidene Dimethoxydimethylindanone, Citrus Aurantium Amara (Bitter Orange) Flower Extract, Zingiber Officinale (Ginger) Root Extract

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BIOSSANCE.:

### SQUALANE + MINERAL SPF 45

BROAD SPECTRUM UVA/UVB FACIAL SUNSCREEN LOTION

45

Protects, Primes & Hydrates Face



C30  
H62

50ML/1.6907 FL. OZ.

BIOLGY BY NATURE.  
HUMAN BY DESIGN.™

#### WHAT IS SQUALANE (C30H62)?

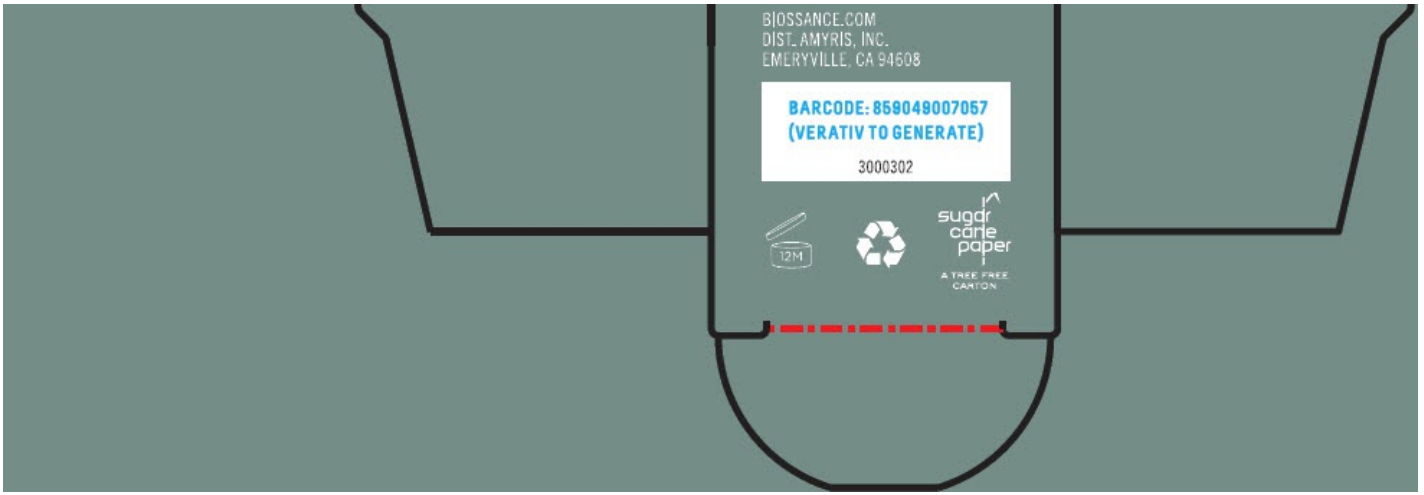
Squalane is our mega-moisturizing molecule that instantly hydrates while locking in essential moisture. Your body produces its own version—but the amount decreases over time.

Our Berkeley-born patented technology creates 100% plant-derived squalane sustainably from sugarcane.



NONTOXIC  
PARABEN FREE  
PHTHALATE FREE  
MINERAL OIL FREE  
SYNTHETIC FRAGRANCE FREE

Dermatologist tested.  
Ophthalmologist tested.  
Non-comedogenic.  
For all skin types,  
including sensitive skin.



## SQUALANE PLUS MINERAL SPF 45

titanium dioxide and zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73517-123
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	40.69 mg in 1 mL
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	70 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Medium-Chain Triglycerides</b> (UNII: C9H2L21V7U)	
<b>Squalane</b> (UNII: GW89575KF9)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Polymethylsilsesquioxane (4.5 Microns)</b> (UNII: 59Z907ZB69)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>STYRENE/ACRYLAMIDE COPOLYMER (500000 MW)</b> (UNII: 5Z4DPO246A)	
<b>Thermus Thermophilus Lysate</b> (UNII: 775R692494)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>Sodium Chloride</b> (UNII: 451W47IQ8X)	
<b>Hydroxyacetophenone</b> (UNII: G1L3HT4CMH)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	
<b>Saccharide Isomerate</b> (UNII: W8K377W98I)	
<b>Caramel</b> (UNII: T9D99G2B1R)	
<b>Pentylene Glycol</b> (UNII: 50C1307PZG)	
<b>1,2-Hexanediol</b> (UNII: TR046Y3K1G)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>Disteardimonium Hectorite</b> (UNII: X687XDK09L)	

<b>Triethoxycaprylylsilane</b> (UNII: LDC331P08E)	
<b>Levomenol</b> (UNII: 24WE03BX2T)	
<b>Benzylidene Dimethoxydimethylindanone</b> (UNII: 75HIF3C97L)	
<b>Citrus Aurantium Flower</b> (UNII: O730ZX2Z83)	
<b>Ginger</b> (UNII: C5529G5JPQ)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73517-123-01	1 in 1 CARTON	03/01/2018	
1		50 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	03/01/2018	

**Labeler** - Amyris, Inc. (185930182)

Revised: 2/2020

Amyris, Inc.