

# **SILKSHIELD ALL MINERAL SUNSCREEN WITH TRIHEX TECHNOLOGY- zinc oxide cream**

**Alastin Skincare, 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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**SilkShield® All Mineral Sunscreen with TriHex Technology®**

## **Drug Facts**

### **Active Ingredients**

Zinc Oxide 19.95%

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

### **Directions**

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - After 40 minutes of swimming or sweating
  - Immediately after towel drying
  - At least every two hours
- 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 10am - 2pm
- Wear long-sleeved shirts, pants, hats and sunglasses

## **Inactive Ingredients**

Dimethicone, Cyclopentasiloxane, Polysilicone-11, Squalane, Polyglyceryl-3 Polydimethylsiloxyethyl Dimethicone, HDI/Trimethylol Hexyllactone Crosspolymer, Methyl Methacrylate Crosspolymer, Triethoxysilylethyl Polydimethylsiloxyethyl Hexyl Dimethicone, Palmitoyl Hexapeptide-12, Palmitoyl Tripeptide-1, Dunaliella Salina Extract, Ectoin, Hydroxymethoxyphenyl Decanone, Tocopherol, Caprylic/Capric Triglyceride, Stearalkonium Hectorite, Disteardimonium Hectorite, Pentaerythrityl Tetraisoostearate, Propylene Carbonate

## **Other Information**

- Protect the product in this container from excessive heat and direct sun. Store at room temperature 15° - 30°C (59° - 86°F).

Distributed by Alastin Skincare<sup>®</sup>, Inc.  
Carlsbad, CA 92010.

## **PRINCIPAL DISPLAY PANEL - 53.8 g Tube Carton**

NDC 70604-030-02

SilkSHIELD<sup>®</sup>  
ALL MINERAL  
SUNSCREEN  
with TriHex Technology<sup>®</sup>

ALASTIN<sup>®</sup>  
SKINCARE

Broad Spectrum SPF 30 Sunscreen  
Water Resistant (40 minutes)

1.9 Oz. 53.8g

0.75000

1.19531



NDC 70604-030-02

SilkSHIELD®  
ALL MINERAL  
SUNSCREEN  
with TriHex Technology®

For sensitive and  
post-procedure skin.

This lightweight,  
fast-absorbing sunscreen  
provides hydration and helps  
provide protection from:

- UVA/UVB rays
- Pollution
- Blue Light
- IR Rays



parabenfree



crueltyfree



glutenfree



reef friendly

ALASTIN  
SKINCARE

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Distributed by Alastin Skincare®, Inc.  
Carlsbad, CA 92010. Made in the USA.  
420 | 6420-01



0.75000

# SILKSHIELD ALL MINERAL SUNSCREEN WITH TRIHEX TECHNOLOGY

zinc oxide cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70604-030
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	0.1995 g in 1 g

## Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
SQUALANE (UNII: GW89575KF9)	
POLYGLYCERYL-3 POLYDIMETHYLSILOXYETHYL DIMETHICONE (4000 MPA.S) (UNII: RLA2U05Z4Q)	
HEXAMETHYLENE DIISOCYANATE/TRIMETHYLOL HEXYLLACTONE CROSSPOLYMER (UNII: WB5K9Y35Y9)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
TRIETHOXSILYLETHYL POLYDIMETHYLSILOXYETHYL HEXYL DIMETHICONE (UNII: X75PL53TZJ)	
PALMITOYL HEXAPEPTIDE-12 (UNII: HO4ZT5S86C)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
DUNALIELLA SALINA (UNII: F401DKI9A6)	
ECTOINE (UNII: 7GXZ3858RY)	
1-(4-HYDROXY-3-METHOXYPHENYL)-DECAN-3-ONE (UNII: BO24ID7E9U)	
TOCOPHEROL (UNII: R0ZB2556P8)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
STEARALKONIUM HECTORITE (UNII: OLV698AH5P)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
PENTAERYTHRITYL TETRAISOSTEARATE (UNII: 9D7IK5483F)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:70604-030-02	1 in 1 CARTON	09/17/2021	
1		53.8 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:70604-030-04	113 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2021	
3	NDC:70604-030-99	12 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2021	
4	NDC:70604-030-00	12 in 1 CARTON	10/01/2021	
4		5 g 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	09/17/2021	

**Labeler** - Alastin Skincare, Inc. (085997348)

**Registrant** - Wasatch Product Development, LLC (962452533)

## Establishment

Name	Address	ID/FEI	Business Operations
Wasatch Product Development, LLC		962452533	MANUFACTURE(70604-030)

## Establishment

Name	Address	ID/FEI	Business Operations
Bentley Labs		068351753	MANUFACTURE(70604-030)

Revised: 9/2022

Alastin Skincare, Inc.